



Analysis of Medical Responsibility for the Risks of Clinical Trials of the TB Vaccine in Indonesia: A Case Study on Legal Protection for Research Subjects

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ABSTRACT

Keywords:

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Legal Protection;
Research Subjects;
Tuberculosis;
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Indonesia is a country governed by the rule of law, which provides legal guarantees and protection for all its citizens, including in matters related to health services. This protection also extends to individuals who participated as subjects in the TB vaccine clinical trials conducted several months ago. These circumstances raise questions regarding the forms of medical and legal responsibility owing to clinical trial subjects when risks arise during or after the research. They also prompt an examination of whether the informed consent procedures and legal safeguards applied in the TB vaccine clinical trials in Indonesia align with the principles of fairness and safety for research participants. This brief study employs a normative juridical approach, relying on secondary data obtained through library research. The findings indicate the following: First, medical and legal responsibilities toward TB vaccine clinical trial subjects in the event of risks occurring during or after the research include the obligation to report such incidents to the Ethics Committee and to accept the consequences of any errors committed. Second, the informed consent mechanisms and legal protections implemented in TB vaccine clinical trials in Indonesia do not fully satisfy the principles of fairness and safety for research subjects.

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INTRODUCTION

As is known, all Indonesian citizens have the right to receive legal protection from the state in the health sector. This right to health is guaranteed by Article 28H of the 1945 Constitution of the Republic of Indonesia (1945 Constitution), which explicitly states that every individual has the right to adequate health services. Furthermore, Article 34 of the 1945 Constitution also affirms the state's responsibility to provide protection to vulnerable community groups, such as the poor and abandoned children. In addition, Article 27 paragraph (2) of the 1945 Constitution also provides a constitutional guarantee that every citizen has the right to get a decent job and a livelihood in accordance with humanitarian standards (Berdame et al., 2024). The protection of people's right to health has a significant correlation with the handling of dangerous diseases, such as Tuberculosis (TB).

Tuberculosis (TB) is still a health problem around the world, including in Indonesia. According to the Global TB Report 2023 released by WHO, Indonesia accounts for around 10% of all TB cases in the world. The report, which was published on November 7, 2023, places Indonesia as one of the two countries with the highest burden of TB in the world, along with India and China. In addition, data from the Indonesian Ministry of Health as of November 3, 2023 recorded that there were 658,543 cases of tuberculosis in Indonesia (Rahma et al.,

2024). Furthermore, Indonesia is indeed facing a difficult situation in efforts to control tuberculosis (TB). As of early March 2025, the Ministry of Health reported that around 889,000 cases of tuberculosis had been successfully discovered, or about 81% of this year's detection target of 1,092,000 cases. With an estimated total of 1,090,000 cases, Indonesia is still ranked as the second country with the highest burden of TB in the world, after India (Hanim, 2025).

Tuberculosis (tuberculosis) is a long-term infection caused by the bacterium *Mycobacterium tuberculosis*, which most often attacks the parenchymal tissue of the lungs. The disease usually starts in the lungs before then spreads to other organs. The incubation period lasts about 2–10 weeks, after which the patient begins to show clinical signs and experience a decrease in immune function. Tuberculosis progresses slowly and can enter a latent phase without symptoms before returning to activity. *Mycobacterium tuberculosis* itself is a rod-shaped, gram-positive, acid-resistant bacterium, and can be recognized through special microscopic staining as acid-resistant bacilli (BTA) (Nurhalisah et al., 2023).

In response to these problems, the Indonesian government has implemented various preventive and anticipatory measures. One of the steps taken is the implementation of TB vaccine trials as a form of fulfilling the right to health for the entire community. However, this pilot program sparked debate and elicited various public responses. Some groups consider that the approval of the TB vaccine trial makes the country seem to make its citizens the object of experimentation, especially with the involvement of figures such as Bill Gates who increasingly spark doubts (BBC News Indonesia, 2025). These concerns show the lack of state protection for the people who are the subject of the vaccine research.

The urgency of this research is underscored by three critical factors: (1) the increasing number of international clinical trials being conducted in Indonesia without adequate oversight mechanisms; (2) recent public controversies surrounding the M72 TB vaccine trials sponsored by the Bill & Melinda Gates Foundation, which have exposed gaps in informed consent practices and transparency; and (3) the absence of comprehensive legal analysis examining the intersection of medical ethics, constitutional rights, and clinical trial regulations in the Indonesian context. Given Indonesia's position as the second-highest TB burden country globally, the ethical and legal implications of these trials carry significant weight for both national health policy and international research ethics standards.

Every individual has the right to have protection for his or her health, and that right includes fundamental rights that cannot be diminished under any circumstances. For a person who is facing a health problem, there is a special right called a patient right. This right provides space for patients to ask for the fulfillment of their health needs, based on moral and ethical values. Patients' rights are part of human rights because they stem from the freedom of each person to make decisions about themselves. In this context, patient rights can be divided into several categories, such as natural rights, political rights, and civil rights (Suhaid et al., 2022). Including the right to refuse or consent to participation in a trial and the implementation of clinical trials carried out.

While several studies have examined informed consent in medical contexts (Gustina et al., 2022; Pebrina et al., 2022) and clinical trial ethics broadly (Kandi & Vadakedath, 2022), these works have not specifically addressed the unique legal and ethical challenges posed by large-scale TB vaccine trials in Indonesia. Previous research by Alfarizi and Listyaningrum (2024) discussed legal protection for health research subjects but did not analyze the specific

regulatory gaps in TB vaccine trials or examine the adequacy of compensation mechanisms when adverse effects occur.

The novelty of this research lies in three key contributions: First, it provides the first comprehensive juridical analysis of medical and legal responsibility specifically in the context of TB vaccine clinical trials in Indonesia, examining both the regulatory framework and its practical implementation gaps. Second, it critically evaluates the informed consent mechanisms used in recent TB vaccine trials against constitutional guarantees and international bioethics standards, revealing specific deficiencies in risk disclosure and participant comprehension. Third, it proposes concrete legal reform recommendations based on identified gaps between existing regulations (Law No. 17 of 2023, BPOM Regulation No. 8 of 2024) and their practical enforcement, particularly regarding accountability mechanisms when research subjects experience adverse effects.

On the other hand, the Indonesian government already has a legal basis to ensure public protection in the implementation of clinical trials, which is contained in Law Number 17 of 2023 concerning Health, various BPOM regulations, and ethical guidelines from the Health Research Ethics Committee (KEPK). Although these principles have been formulated, their implementation and oversight at the field level still often raise questions. In fact, there are still many research participants who do not fully understand the important information on which conscious consent is based, including about possible risks, possible benefits, stages of the procedure, and rights they have during clinical trials (Kandi & Vadakedath, 2022).

Based on the descriptions that have been briefly presented previously, this study aims to analyze juridically and ethically the responsibility of the medical sector for the risks experienced by the subjects of the tuberculosis vaccine clinical trial. In addition, this study also aims to determine the effectiveness of the implementation of *informed consent* and the form of legal protection provided to clinical trial subjects, in the context of policies and regulations in Indonesia related to the TB vaccine trial itself. Thus, the problem in this brief research is how the form of medical and legal responsibility for the subjects of the TB vaccine clinical trial when there is a risk during or after the research, as well as whether the informed consent mechanism and legal protection applied in the TB vaccine clinical trial in Indonesia have met the principles of justice and safety for the research subjects.

The benefits of this research include: (a) Academic benefit: contributing to the body of knowledge on bioethics and health law in Indonesia, particularly regarding clinical trial regulations and research subject protection; (b) Practical benefit: providing evidence-based recommendations for policymakers, ethics committees, and clinical trial sponsors to improve informed consent procedures and accountability mechanisms; (c) Social benefit: enhancing public awareness of research subjects' rights and strengthening advocacy for vulnerable populations participating in clinical trials.

METHOD

This study adopted a normative juridical research approach, examining law as a system of norms through the analysis of regulations, principles, and doctrines. It utilized secondary data via library research, with a prescriptive-analytical design that aimed to assess existing legal frameworks governing clinical trials and provide recommendations for legal improvement, ensuring alignment with constitutional principles and bioethical standards.

The data consisted of primary legal materials, including the 1945 Constitution, the Health Law, BPOM regulations, and the Civil Code, alongside secondary materials such as academic journals, books, and international guidelines. Tertiary materials, like legal dictionaries, provided additional support. Data collection was conducted through systematic library research, involving the inventory, classification, and critical analysis of these legal sources to identify key provisions and regulatory gaps.

Analysis employed legal interpretation methods—grammatical, systematic, historical, and teleological—to examine the extent of medical responsibility for vaccine trial risks. The process involved identifying relevant norms, comparing Indonesian regulations with international standards, assessing legal consistency, and analyzing gaps between formal law and practical implementation. Validity was ensured through source and theory triangulation, peer review, and logical consistency, while research ethics emphasized accurate citation, objective analysis, and sensitivity toward vulnerable populations in clinical trials.

RESULTS AND DISCUSSION

The Concept of Medical Responsibility in TB Vaccine Trials

The definition of clinical trial, as explained in Article 1 of BPOM Regulation Number 8 of 2024 concerning Procedures for Approval of the Implementation of Clinical Trials, is research involving human subjects who receive a product with the aim of discovering or ascertaining clinical, pharmacological and/or other pharmacodynamic effects, and/or identifying unwanted reactions, and/or studying the absorption process, distribution, metabolism, and excretion to ensure the safety and/or efficacy of the product being studied.

However, not all individuals are required to receive the vaccine. For example, individuals with severe medical conditions that prevent them from receiving vaccines are highly dependent on high levels of vaccination coverage in their surrounding communities. This aims to reduce the potential for disease transmission (Peraturan Badan Pengawas Obat dan Makanan, 2024). Thus, the concept and mechanism for implementing TB vaccine trials in Indonesia need to be carried out with very careful preparation and consideration (Irham et al., 2024).

Vaccination is a biological process that aims to build immunity to certain diseases through the administration of vaccines. This process is done by inserting a vaccine into the body to stimulate the immune system to form an active immune response. That way, a person who has been vaccinated will have protection against infection or at least experience much milder symptoms if exposed. When the pathogen enters the body, the previously formed antibodies will immediately work against the disease-causing agent. Therefore, vaccine recipients generally do not experience severe conditions, considering that their bodies already have specific defenses from the vaccine given (Tribakti et al., 2022).

In an effort to provide legal protection to the right to health, every citizen participates in global initiatives to eliminate TB through its involvement in the *End TB* strategy. This strategy sets a target to reduce the TB death rate by 90% by 2030, when compared to 2015 data, as well as a reduction in the incidence rate by 80% by 2035. In addition, by 2030, it is hoped that no more families will experience financial difficulties due to catastrophic medical costs caused by this disease. To achieve this goal, *the End TB* strategy relies on various

innovations, including the development of TB vaccines and therapies with shorter and effective treatment durations (Kementerian Kesehatan Republik Indonesia, 2020).

Therefore, efforts to handle and control tuberculosis in Indonesia should comprehensively consider various essential aspects related to the right to health of every citizen. The main concern should be focused on the effects that may arise from the TB vaccine trial on the community. Thus, the implementation of the TB vaccine trial is expected to provide more significant benefits than the potential harm that may occur.

As mentioned in the previous section, tuberculosis is a chronic infectious disease that is transmitted through the air, and until now it is still a serious challenge in the field of global public health. Indonesia is one of the countries with a relatively high number of TB cases globally. The disease is caused by *Mycobacterium tuberculosis*, as well as several other species of the genus *Mycobacterium* such as *M. africanum*, *M. bovis*, *M. leprae*, and other species, all of which belong to the group of Acid-Resistant Bacilli (BTA) (Rahma et al., 2024). The concept of medical responsibility in TB vaccine clinical trials should pay attention to the scope of the rights of the people involved in the TB vaccine trial.

The TB vaccine trial is indeed a form of research that involves humans as subjects. The explanation of Article 335 paragraph (4) of the Health Law states that research on humans must be carried out by paying attention to the health and safety aspects of the subject concerned. Research and development that uses humans as subjects must obtain informed *consent*. Before obtaining such consent, the researcher must provide information about the purpose of health research and development and the use of the results, the guarantee of confidentiality of identity and personal data, the methods used, the risks that may arise, and other things that the subject needs to know in the context of health research and development (Undang-Undang Nomor 17 Tahun 2023).

At this stage, the medical community should have considered and predicted the situation and condition of the research subject, from the beginning of being recruited as a "guinea pig" to the possible reactions and effects that would be experienced. The trial must obtain approval from the KEPK, through strict evaluation, and be carried out transparently to ensure that the interests of the participants remain a priority. In fact, in Article 335 paragraph (5) of the Health Law, it is stated that all research involving humans as subjects must be based on four general ethical principles, namely respect *for persons* which aims to respect autonomy and protect individuals with impaired or limited autonomy, *beneficence* and *nonmaleficence*, and justice (Undang-Undang Nomor 17 Tahun 2023).

The implementation of TB vaccine clinical trials must be based on four fundamental principles in bioethics: *First*, the principle of autonomy requires that each participant voluntarily give consent after obtaining clear and comprehensive information regarding the benefits and potential risks. *Second*, the principle of virtue directs research to maximize the benefits obtained by participants while minimizing the risks. *Third*, the principle of *non-maleficence* requires that research does not cause unnecessary harm. Finally, the principle of fairness emphasizes the fair selection of participants and the equitable distribution of benefits from research results (Hastowo, 2025). These four principles are the main responsibility of medical personnel in the implementation of TB vaccine clinical trials which must ensure the principles of autonomy, virtue, non-harm, and justice. This includes providing clear information about the purpose of research and health development and the use of its results,

ensuring the confidentiality of identity and personal data, methods used, potential risks, and other matters that the research subject needs to know, so that legal protection for each participating individual, whether voluntarily or due to elements of state coercion, can be fully fulfilled.

Informed Consent as Legal Protection of Research Subjects

The implementation of health research involves collaboration between researchers, research participants, and other related parties. In conducting research, researchers are required to comply with ethical norms and applicable legal provisions to ensure the safety and welfare of research subjects (Alfarizi & Listyaningrum, 2024). The involvement of participants in this health research requires strong legal protections including human rights, confidentiality of personal data, protection against risks that may arise during the study, and protection from unlawful actions. Researchers are required to ensure that participants clearly understand the objectives, methods, and potential risks of the study before participating. Consent given must be voluntary, transparent, and based on complete information without any element of coercion (Alfarizi & Listyaningrum, 2024).

On the other hand, there are also people who reject the vaccine trial. For the community group that refuses, this clinical trial is considered nothing more than a government game. Some even consider that Indonesians are simply used as "guinea pigs". This sentiment was also reinforced by the traumatic experience during the Covid-19 pandemic in 2019. Another concern that triggered the rejection was safety issues and the possibility of side effects from the M72 vaccine. Even though the vaccine has gone through a number of stages of testing that are considered safe, some people are still skeptical about the risks that may arise during the clinical trial process. In addition, there are also concerns about the potential exploitation or new forms of biomedical colonialism, mainly due to the interference of outside parties, including the Bill & Melinda Gates *Foundation* (Nisa & Zakiyah, 2025).

An important factor that affects a patient's willingness to be a research subject is the quality of the explanation provided by the doctor or medical personnel who are also acting as researchers. If the information presented in the informed consent process is incomplete or appears to be hidden, this may cause the patient to refuse to participate in the study (Alfarizi & Listyaningrum, 2024). Legal protection against them also depends heavily on the extent to which the medical personnel involved in the TB vaccine trial carry out their obligations ethically and professionally.

As mentioned earlier, the Health Law also contains provisions regarding legal protection for individuals involved in research. Article 335 paragraph (4) emphasizes that every research involving humans is obliged to pay attention to health and safety aspects, obtain consent from participants, and ensure that the party concerned has received adequate information about possible risks, benefits, and reactions that may arise during the trial. Furthermore, Article 335 paragraph (5) emphasizes that research involving human beings as subjects must be based on respect for the autonomy, dignity, and dignity of individuals, as well as ensuring protection for them. Overall, these provisions are a form of legal security given to the research subjects (Undang-Undang Nomor 17 Tahun 2023).

Informed consent is consent given by the patient voluntarily and with full awareness after obtaining complete, legal, and accurate information about the condition and medical

measures from the doctor. Therefore, informed consent serves as a mechanism to prevent fraud or coercion, as well as limit the authority of doctors to protect the interests of patients (Kamila et al., 2025). In other words, informed consent is also a means of legal protection for patients and doctors. However, in an emergency, even if the top priority is to save the patient's life, informed consent is still an important aspect, although its implementation can be reduced. Based on Article 293 paragraph (5) of the Health Law, every medical procedure should ideally be carried out after the patient or his or her family member who represents gives consent based on a thorough explanation of the diagnosis, purpose of the action, available alternatives, potential risks, possible complications, and the estimated outcome of the action (Kamila et al., 2025).

Regarding the issue of informed consent, consent can be given both in writing and orally. If the patient has received an explanation from the doctor and consents to the information, then medical procedures such as medication, routine treatment, or surgery can be carried out based on the patient's consent as part of informed consent. This condition is also closely related to the principle of autonomy owned by the patient. Basically, the principle of autonomy emphasizes that patients have the right to accept or reject information provided by health workers in the informed consent process. This principle is also a guideline that requires medical personnel to convey information transparently, respect privacy, maintain data confidentiality, and obtain consent from patients or family members before taking any medical action.

The submission of informed consent is one of the main aspects of medical ethics, especially related to the implementation of TB vaccine trials in Indonesia. Every research that involves humans as subjects must be based on three main ethical principles, namely respect for persons, beneficence, and justice. Based on these principles, research should be carefully designed with a focus on maximizing benefits as well as minimizing risks and potential errors. All research participants must be treated with respect and fairness in accordance with applicable moral values. Research should not be based on the personal interests of researchers or institutions, but should be directed for the benefit of participants and contribute to the advancement of science, reduce suffering, or improve the quality and expectation of human life (Syahpura, 2018). All of these principles reflect medical ethics that are attached to the obligation to provide informed consent by medical parties.

Especially considering that Indonesia is actively involved in the implementation of three vaccine clinical trials where the first vaccine is the result of a collaboration between the Bill & Melinda Gates Foundation (BMGF) and the British pharmaceutical company, GSK, which uses recombinant protein technology. The second vaccine was developed through a collaboration between Chinese pharmaceutical company, CanSinoBio, and Indonesian biopharmaceutical company, Etana, by utilizing viral vectors, and is currently in the first phase of clinical trials. Meanwhile, the third vaccine is the result of the development of a German biotechnology company, BioNTech, together with an Indonesian pharmaceutical company, Biofarma, which uses mRNA technology and is looking for a second phase clinical trial location in Indonesia. These three vaccines are targeted to be completed in 2025 and begin distribution in 2026 (Sari et al., 2024).

The Role of the Ethics Committee in the Case of Side Effects of TB Vaccine Trial Subjects

The Head of BPOM of the Republic of Indonesia emphasized that the side effects of the tuberculosis vaccine developed by Bill Gates do not endanger life safety. According to Taruna, in phase 1 and 2 clinical trials, the side effects that appeared were generally in the form of increased body temperature or fever, so it was seen by the government as not endangering the study subjects, although some participants gave different responses (Janati & Prabowo, 2025).

A member of the public who was the subject of the vaccine trial said that he felt side effects in the form of pain and soreness in the area of the injection site (Supriatin, 2025). However, in a number of literature it is stated that TB vaccine trials can trigger systemic reactions, where some participants may experience symptoms such as fever, fatigue, muscle aches, or headaches after receiving the vaccine (Romadona, 2025). Side effects felt by the study subjects are generally in the form of mild symptoms that have not been taken seriously, such as increased body temperature (fever), pain and aches, fatigue, muscle pain, and headaches. Side effects in some of the TB vaccine clinical trial participants generally have not attacked vital organs. However, it is possible that other effects that are quite severe occur in several areas of the trial and are experienced by the people who are the subject of the research.

The implementation of TB vaccine trials in Indonesia is inseparable from the role of KEPK. As mentioned in previous sections, the trial must involve approval from the KEPK, rigorous evaluation, and transparency of implementation, ensuring that the interests of the participants come first. In other words, this is the role of the Ethics Committee (in this case KEPK) in the implementation of the TB vaccine trial itself.

Based on the provisions of Article 1 paragraph (11) of BPOM Regulation Number 8 of 2024 concerning Procedures for Approval of the Implementation of Clinical Trials, the Ethics Committee is an independent institution consisting of medical/scientific professionals and non-medical/non-scientific members in the field of Clinical Trials, which is responsible for the protection, rights, safety, and welfare of clinical trial subjects. The Ethics Committee also has the authority to approve or reject PPUK (Approval of the Implementation of Clinical Trials) as stipulated in Article 6 paragraph (3) of the 2024 BPOM Regulation (Peraturan Badan Pengawas Obat dan Makanan, 2024). The KTDS (Serious Unwanted Incident) report must be submitted to the Ethics Committee in accordance with Article 22 paragraph (1) letter b of the 2024 BPOM Regulation (Peraturan Badan Pengawas Obat dan Makanan, 2024). In addition, the Ethics Committee is authorized to stop the ongoing Clinical Trials without their consent. Regarding the illustration of side effects experienced by previous participants, the organizer can only report them if the side effects cause serious consequences for the research subjects or are classified as KTDS (Serious Unwanted Events).

In addition, in another part of the BPOM 2024 Regulation, it is emphasized that the Ethics Committee is an independent body—either in the form of a review board or a committee at the institutional, regional, national, or supranational level—consisting of medical professionals and non-medical members, who are tasked with ensuring the protection of the rights, safety, and welfare of human subjects in clinical trials. It is also responsible for providing assurances to the public regarding such protections by reviewing and approving or providing support for clinical trial protocols, researcher feasibility, facilities, and methods and materials used to obtain and document the conscious consent of clinical trial subjects. Although

the legal status, composition of the membership, functions, working mechanisms, and regulatory requirements of the Ethics Committee may differ from country to country, the Ethics Committee must operate in accordance with the principles of the CUKB as described in this guideline. In fact, a clinical trial must be carried out according to a protocol that has received approval or support from the Ethics Committee.

The Ethics Committee is obliged to maintain the rights, safety, and welfare of all Clinical Trial Subjects. Extra protection needs to be provided, especially in clinical trials involving subjects from vulnerable groups. In other words, the Ethics Committee is also responsible for legal protection for each subject in the clinical trial research, so that the implementation of the TB vaccine trial can run while still prioritizing legal protection for each participant. Based on the descriptions that have been briefly stated earlier, it can be understood that the Ethics Committee has a strategic role in a clinical trial, in this case the TB vaccine trial in Indonesia. Approval of the implementation is in the hands of the Ethics Committee, including the responsibility to ensure legal protection for the research subject in the implementation of the clinical trial itself.

Informed Consent Procedure and Its Validity

Informed consent can be understood as one of the prerequisites for the occurrence of a therapeutic agreement, although it is not the only condition for the validity of the agreement. This is because according to Article 1320 of the Civil Code, there are four other conditions that must also be met for an agreement to be considered valid (Pebrina et al., 2022). The four conditions are agreement, skill, a certain thing, and a halal cause. The informed consent procedure relies on interaction between the medical party and the patient or clinical trial participant. This procedure occurs between the vaccine trial implementer and the research subject. In the relationship between doctor and patient, both must be based on two fundamental rights, namely the right to self-determination and the right to information. Therefore, in the implementation of informed consent procedures, the delivery of information by doctors is a crucial element that patients must accept before deciding what is best for them. In addition to providing adequate information, the doctor must also ensure that the patient truly understands the information.

Informed consent is a form of agreement between medical personnel and patients, as well as between the organizer of the TB vaccine trial and the community that is the subject of the research. Informed consent is the main condition in the formation of therapeutic agreements because it is based on two fundamental human rights, namely the right to control one's own destiny and the right to obtain information. From the point of view of biomedical ethics, informed consent is a procedure that reflects the principle of autonomy, in which each individual has the right and freedom to determine and make medical decisions for himself. The ethical foundation of informed consent lies in the doctor's obligation to respect the patient's independence. However, for a person to be considered to have autonomy, he must have competence in choosing actions and making decisions on his own.

In TB vaccine trials, the procedure generally begins with providing information by the medical community to the people who are the subject of the research, both orally and in writing. This procedure has similarities with the conditions for the validity of the agreement as stipulated in Article 1320 of the Civil Code, which requires the existence of an agreement, the

competence of the parties, certain objects, and halal causes. Based on this, the main procedure in informed consent must be based on the agreement reached between parties representing the government in the TB vaccine trial and the community as the subject of the study. This agreement must be based on the subject's proficiency, whereby the individual concerned receives information in a conscious and non-coercive state, regarding compensation, benefits, and risks that may arise during and after the research process.

However, the agreement manifested in informed consent emphasizes more on the will of the research subject alone, not the result of an understanding between the two parties, namely the researcher and the research subject. The implementation of TB vaccine trials on new subjects can be carried out after the consent of the subject. However, in practice, the community as research subjects is often in a weak position, because they do not necessarily have an adequate understanding of information regarding TB vaccine trials, both in the context of their current benefits and future impacts, in addition to only hoping that the vaccine can cure the disease or prevent TB infection.

The validity of this will be compromised if the organizer of the TB vaccine trial does not provide information transparently, but only promises that the subject will be protected from exposure to the TB virus or provide hope of recovery for the sufferer. When the research subject only understands that the test action of this vaccine will prevent infection or cure the disease he suffers from, but in fact he is still infected or has the virus, then the validity of the trial becomes questionable because the information conveyed is distorted and seems misleading.

Especially when the organizers of the vaccine trial commit misleading actions against people in vulnerable conditions, who are structurally in a weak position so that they cannot give consent freely and without pressure. Therefore, the validity of informed consent is highly dependent on the good faith of the TB vaccine trial organizers in conveying information transparently and upholding the principle of voluntary consent from the people who are the subject of the research, not by misleading or falsifying information as if they had given consent.

If a medical action produces an unintended impact, then medical personnel should be held accountable, including in the context of TB vaccine trials involving the Indonesian people as research subjects; if side effects arise that endanger the research subject, then it must be reported to the Ethics Committee. Regarding side effects in TB vaccine trials, organizers are required to conduct a thorough risk identification. All side effects and potential dangers of vaccines must be clearly understood and communicated transparently to clinical trial participants. In addition, the organizers bear full responsibility in the event of health problems during or after the implementation of the trial. Thus, trial organizers, including researchers, research institutions, and sponsors, have the primary responsibility to ensure the safety of participants and minimize the risk of side effects to the maximum (Redaksi Analognews, 2025).

In addition, if serious side effects occur, clinical trial organizers may be held legally liable, both criminally and civilly, depending on the type and severity of the effects caused. Therefore, organizers must ensure that each participant of the TB vaccine clinical trial is in a consistent physical condition from the beginning to the end of the clinical trial. The risk of exposure to side effects, no matter how small, must be communicated to all the people who are the subject of the study, including the consequences of the most severe side effects; Because the concern that often arises in the public's mind is the lack of transparency of the organizers in providing comprehensive information about the potential side effects.

Legal Analysis and Responsibility for Violation of the Rights of Research Subjects

The most fundamental right possessed by the research subject is to obtain clear information about the compensation, benefits, and risks or side effects that may arise as a result of participation in TB vaccine trials. Violations of these rights are a form of legal and ethical violations, especially when they are committed against individuals who are directly the subject of the research, even more so if they are in vulnerable conditions that do not allow for maximum consent. In the event of a case of serious side effects, the organizers can be held legally liable, both criminal and civil, to unlawful acts (PMH) that cause real losses to individuals affected by the vaccine trial. The consequences of violations of the rights of research subjects can place the medical community or the organizers as parties who must be legally responsible. Accountability should be carried out through legal mechanisms, although most medical circles or trial organizers have the potential to avoid legal snares if there is a settlement through mediation with the victim, which is carried out outside the formal judicial channels.

Furthermore, if the adverse effect causes damage or health impairment, the clinical trial participant is entitled to compensation or medical treatment proportionate to the severity of the impact experienced. Legal liability for side effects in clinical trials of tuberculosis vaccines, in particular BCG vaccines, is subject to the provisions of civil law and health law. This responsibility includes parties involved in the clinical trial process, such as researchers, sponsors (e.g. the Gates Foundation), as well as health oversight agencies. Based on the provisions of Articles 1365 and 1366 of the Civil Code (KUHPerdata), if a doctor or medical personnel commits an unlawful act in carrying out his profession so as to cause harm to the patient, then the person concerned is obliged to provide compensation and be responsible for losses arising from the negligence of the medical act (Gustina et al., 2022). Actions as referred to in this article also include the provision of informed consent that is not transparent, dishonest, or contains elements of mislead against the research subject.

Providing information and consent for medical actions (informed consent) is a legal obligation that must be fulfilled by every hospital or health service facility before carrying out medical measures, including by the organizers of TB vaccine clinical trials. Medical personnel are obliged to provide a comprehensive explanation to the research subject regarding the condition faced, the medical procedures to be performed, potential side effects, and risks that may arise from these actions. If this obligation is ignored, the organizer of the TB vaccine clinical trial may be subject to legal consequences, both criminal and civil.

In general, research subjects are also entitled to receive financial compensation as a form of appreciation for time, effort, travel, and inconvenience that may be experienced during their involvement in the research. The amount of compensation may vary, depending on the type and phase of the clinical trial, the duration of the study, and the medical procedure performed. It is important to ensure that compensation is provided proportionately and fairly to encourage voluntary participation without placing an undue economic burden on the study subjects (CISCRP, 2021).

In Appendix 1 number 17 of the BPOM Regulation of 2024, it is emphasized that all clinical trial subjects are required to receive compensation from sponsors, which can be in the form of insurance in the event of injuries related to the implementation of clinical trials. The statement regarding compensation or insurance must be clearly included in the information

submitted to the prospective subject. In addition, the clinical trial organizer is also obliged to provide information to the Ethics Committee regarding payments and forms of compensation available to subjects. This regulation also stipulates that if the clinical trial subject receives compensation, the mechanism and procedures for granting it must be in accordance with the provisions of applicable regulations, including in the event of an accident during the research process.

The Health Law also provides information about compensation, although it is very limited. Among them in Article 405 of the 2023 Health Law that;

1. The Central Government, Regional Governments, and/or related private parties are responsible for funding arising in the event that there are adverse events after the administration of mass prevention drugs and immunization in disease control, including the management of KLB and Outbreaks.
2. The funding as intended in paragraph (1) is at least used for: a. causality audit; b. Health services, including medical rehabilitation; and c. compensation to the victim.

Compensation to victims is a form of compensation, as explained in the explanation of the regulation, that what is meant by "compensation to victims" is compensation in the form of disability compensation or death compensation given to individuals who experience adverse events after the administration of mass prevention drugs and immunization, based on the results of causality audits.

In addition, the provisions regarding compensation are also stipulated in Article 407 of the 2023 Health Law that:

1. The Central Government, Regional Government, and/or the community can provide funding assistance in order to improve and provide Health Services to the community.
2. Funding assistance from the Central Government, Regional Government, and/or the community as intended in paragraph (1) shall be carried out in accordance with the provisions of laws and regulations.

The explanation of the article states that funding assistance includes, among other things, assistance or compensation for people affected by KLB or Outbreak control activities. However, the two regulations do not explain in detail the procedures and mechanisms for providing compensation.

CONCLUSION

This study concludes that medical and legal responsibilities for TB vaccine clinical trial subjects in Indonesia, in cases of risks during or after the study, entail obligations to report incidents to the Ethics Committee and accept consequences for errors. However, the informed consent mechanisms and legal protections applied have not fully met principles of justice and safety, as most information provided omitted the highest risks to participants. Consequently, stricter regulatory strengthening, codified liability provisions for criminal and civil violations, systematic monitoring, and rigorous government oversight of informed consent are essential to ensure transparent, accountable processes upholding transparency, fairness, and participant rights. For future research, scholars could conduct empirical studies comparing Indonesia's clinical trial frameworks with successful international models, such as those in the EU or WHO guidelines, to develop evidence-based policy reforms.

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