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Clinical Trial of Tuberculosis Vaccine in Indonesia: Balancing Public Health Needs and Legal Protection for Research Subjects

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ABSTRACT

Clinical trials are an important instrument in the development of science and technology in the health field that aims to produce safe and effective medical interventions. The implementation of research involving human subjects cannot be carried out without clear guidelines, ethical standards, and legal frameworks. In the Indonesian context, various stages and procedures have been established to ensure that clinical trials, including Tuberculosis (TB) vaccine clinical trials that have been carried out, run in accordance with legal principles and medical ethics. This study uses a normative juridical method by relying on secondary data through library research. The focus of the analysis is directed at laws and regulations, public policies, and official documents that regulate the management of vaccine clinical trials in Indonesia. The results of the study show that: first, the implementation of TB vaccine clinical trials in Indonesia must be based on the provisions of national health law by upholding the principles of utility, morality, religious values, moral norms, and oriental norms, as well as compliance with all relevant laws and regulations; second, public health interests can be the basis for restricting individual rights in the implementation of clinical trials, as long as there is strong scientific evidence regarding the potential for the rapid and dangerous spread of infectious diseases, so that the action is proportionate and has legal legitimacy.

Keywords: legal protection; research subject; clinical trials; tuberculosis vaccine

INTRODUCTION

Tuberculosis (TB) remains a major challenge for the health of the world's people, including in Indonesia (Pradipta et al., 2021; Saktiawati & Probandari, 2025). This country is among the top three contributors of TB cases globally, along with India and China. According to the Global TB Report 2023 report from WHO, around 10% of TB cases worldwide originate from Indonesia (World Health Organization, 2023). Indonesia is one of the countries with the highest number of TB cases in the world, so various strategic steps are needed, including the implementation of the TB vaccination program, as part of a more comprehensive countermeasure effort.

Tuberculosis is actually a preventable and generally treatable disease. However, in 2022 tuberculosis became the second highest cause of death in the world due to one type of infectious agent, is just below the coronavirus (COVID-19), and causes almost twice as many deaths as HIV/AIDS. Every year, more than 10 million people are still infected with this disease. Swift and intensive action is needed to stop the global TB epidemic by 2030, in line with the commitments that have been set by the member states of the United Nations (UN) and the World Health Organization (WHO) (World Health Organization, 2023).

The government continues to strive to reduce the number of TB cases in Indonesia. The government's commitment to handling TB cases is shown by improving the detection and reporting system, resulting in the highest case notification in history since 2022. In addition, the government is also developing treatment therapies and starting the use of tuberculosis vaccines. Through Presidential Regulation No. 67 of 2021, the Indonesian government has established policies by carrying out a comprehensive TB control strategy (Nisa & Zakiyah, 2025).

TB disease not only reduces the capacity of health services in Indonesia, but also has significant social and economic consequences for the community. In recent times, various reports have stated that Indonesia has become one of the countries chosen for the implementation of the TB vaccine clinical trial. The information then triggered a critical response from some circles who thought that the government seemed to make the public an object of vaccine testing attributed to the development by Bill Gates (BBC News Indonesia, n.d.).

In the initial stage of the clinical trial which took place a few months ago, as many as 2,095 Indonesians participated as participants out of a total of 20,081 participants recruited in the five countries organizing the study. At the national level, a number of institutions actively contributed to this clinical trial process, including the Friendship Center General Hospital, the Faculty of Medicine, Padjadjaran University, the Faculty of Medicine, University of Indonesia, in collaboration with the University of Indonesia Hospital, and the Cempaka Putih Islamic Hospital in Jakarta (BBC News Indonesia, n.d.). Based on this, it is necessary to pay attention to how legal and ethical aspects relate to legal protection, compensation, as well as benefits and risks that may arise, in the context of biotechnology research or clinical trials in Indonesia.

On the other hand, there are also concerns about the extent to which the rights of citizens who are participants in the vaccine clinical trial are really protected. This concern is further strengthened because every Indonesian citizen has the right to a decent degree of health, which is a basic right and should not be reduced under any circumstances. The guarantee of this right to health is stated in Article 28H paragraph (1) of the Constitution of the Republic of Indonesia of 1945, which affirms that everyone has the right to health services (Berdame et al., 2024).

Based on the principle of fulfilling the rights of the community, it can be understood that various cynical statements have emerged that highlight that the government and the state seem to provide space for their people to be used as subjects in TB vaccine trials. This gives the impression of overriding respect for people's rights, including legal and ethical aspects. Including as a citizen or as a patient, to give consent consciously or even to refuse it. Patients' rights refer to the authority that individuals have to demand the fulfillment of their needs, which are based on ethical and moral principles. This right is an integral part of human rights, which are rooted in the fundamental right of every individual to make decisions independently. In this context, patient rights include several categories, including natural rights, political rights, and civil rights (Suhaid et al., 2022). This includes the right to express rejection or give consent to participation in TB vaccine trials or the implementation of clinical trials conducted.

Indonesia actually has a legal basis that regulates the implementation of clinical trials, both through Health Law Number 17 of 2023, regulations issued by the Food and Drug Supervisory Agency (BPOM), and ethical guidelines from the Health Research Ethics Committee (KEPK). However, the implementation and supervision of these provisions in the field still often raise questions. It is not uncommon to find that research participants do not fully understand the important information that is the basis for providing informed consent, including about the potential risks, benefits, procedures, and rights of them during clinical trials (Kandi & Vadakedath, 2022).

The clinical trial itself, according to Article 1 paragraph (1) of BPOM Regulation Number 8 of 2024 concerning the Procedure for Approval of the Implementation of Clinical Trials, is any research involving human subjects who receive a product in order to find or confirm clinical, pharmacological and/or other pharmacodynamic effects, and/or identify any unwanted reactions, and/or study the absorption process, distribution, metabolism, and excretion to ensure the safety and/or efficacy of the product being studied. In other words, the TB vaccine trial or vaccination is categorized as a form of clinical trial involving the Indonesian people as the subject.

In addition, various studies have proven that vaccination is an effective way to stimulate the body's immune response, so that it can provide safe and efficient protection against various diseases, both mild and potentially severe. The immunization mechanism works by utilizing the body's natural defense system to form immunity to certain infections, while strengthening the immunity of the community as a whole through the concept of herd immunity (Irham et al., 2024). In addition to providing protection to each individual, vaccination programs also play an important role in stopping the chain of transmission and protecting the most vulnerable groups of people—including in the context of TB vaccination.

For individuals with serious medical conditions who are unable to receive the vaccine, their protection is highly dependent on the level of vaccination coverage in the surrounding environment to reduce the rate of disease spread (Tribakti et al., 2022). Vaccination is a biological process by which a person acquires immunity to a particular disease through the administration of vaccines. In this mechanism, the vaccine is injected into the body to stimulate the immune system to work more actively and strongly, so that individuals who have been vaccinated have better protection from the possibility of being infected, or only experience mild symptoms when exposed. When people who have received the vaccine are infected, the antibodies that have been formed will immediately respond and fight the pathogen that causes the disease.

In addition, Indonesia is taking part in global efforts to end TB through the End TB strategy. This strategy targets a reduction in the death rate due to tuberculosis by up to 90% by 2030 compared to 2015 data, as well as a reduction in the number of cases by 80% by 2035. Thus, by 2030, it is hoped that no more families will have to bear the burden of catastrophic costs due to the disease. In its implementation, the End TB strategy emphasizes the need for various breakthroughs, including the development of new vaccines and TB drugs with shorter treatment times, to support the achievement of these targets (Ministry of Health of the Republic of Indonesia, 2020).

The Government of Indonesia also affirmed its commitment to building the quality of healthy human resources by expanding the reach and improving the quality of health services as part of efforts to realize universal health coverage. Comprehensive handling of tuberculosis is one of the important elements to support the formation of superior and highly competitive human resources, so that it is in line with the national development priorities for 2020–2024 listed in the 2020–2024 RPJMN. In line with the document, the TB control program is also a major part of the direction of the national health development policy and strategy 2020–2024, which is within the framework of the 2005–2025 Long-Term Health Development Plan (RPJPK) prepared by the Ministry of Health of the Republic of Indonesia (Ministry of Health of the Republic of Indonesia, 2020).

In the implementation of TB vaccine clinical trials, ensuring legal protection for people who are research participants is very important. Such protection can be realized by providing complete information regarding compensation, potential risks, and benefits that may arise from their involvement in the research. However, information inequality, unbalanced power relations between researchers and participants, and social and economic pressures often make aspects of legal protection for clinical trial subjects neglected. In fact, in modern biomedical practice, respect and protection of the rights of research participants are basic principles that must be fulfilled (Notoadmodjo, 2024). Therefore, everyone involved as a participant in the TB vaccine clinical trial needs to rationally understand the various consequences, both benefits and potential risks, of their decision to participate as a research subject in the scientific process.

Thus, the issues that arise in the implementation of clinical trials require a thorough and balanced critical analysis, taking into account public health aspects, the legal dimension—both legal protection and health law—and ethical principles. Every decision that concerns the life and rights of individuals, especially in the context of medical research, must be based on the *precautionary principle* and uphold the values of transparency and accountability.

Based on all the points that have been stated in the previous section, the problem raised in this research is how the implementation of TB vaccine clinical trials in Indonesia is reviewed from the legal and protection aspects of the research subject and, to what extent the public health interest can be justified to override individual rights in the context of clinical trials in Indonesia.

Based on a comprehensive understanding of the various issues outlined previously, this research aims to analyze the implementation of Tuberculosis (TB) vaccine clinical trials in Indonesia from the perspective of law and the protection of research subjects. Specifically, the purpose of this study is to examine the extent to which the existing legal and policy frameworks, including the Health Law, regulations from the Food and Drug Monitoring Agency (BPOM), and research ethics guidelines, are able to guarantee the protection of the rights, safety, and welfare of citizens participating as trial subjects. Furthermore, this research also seeks to explore the legally justifiable limits between the broader public health interest and individual human rights within the context of clinical trial implementation, particularly in situations involving outbreaks or rapidly spreading infectious diseases.

The expected benefits of this research are twofold. Academically, the study's findings are hoped to contribute to the development of health law scholarship, specifically regarding issues of biomedical research ethics and the protection of research subjects in Indonesia. Practically, the findings and recommendations from this research can serve as consideration for the government, regulators such as BPOM and the Health Research Ethics Committee (KEPK), as well as clinical trial practitioners in the field, to strengthen oversight systems, enhance transparency, and ensure that every stage of TB vaccine clinical trials—or similar research in the future is conducted while upholding the principles of justice, safety, and human dignity, and in accordance with Indonesian legal, moral, and cultural values.

RESEARCH METHOD

This study used a normative juridical approach method by utilizing secondary data through literature studies. It focused on the review of laws and regulations, public policies, and various official documents related to the implementation of vaccine clinical trials, including regulations on the protection of people's rights to health. Data from all these sources were collected, selected, and identified based on their relevance to the research problem. Furthermore, the data were analyzed in an analytical descriptive manner to describe and critically examine the function of existing legal and policy instruments in supporting the implementation of ethical TB vaccine clinical trials and protecting the research subjects. The analysis was carried out in an analytical descriptive manner to describe the extent to which the current legal instruments and public policies have functioned optimally in supporting the implementation of TB vaccine clinical trials for the Indonesian people.

RESULTS AND DISCUSSION

Public Health Interests vs Human Rights and Health

Tuberculosis is a chronic infectious disease that can be transmitted through the air (airborne) and until now is still a major problem in public health at the global level. Indonesia itself is one of the countries with a large contribution to the high number of tuberculosis cases in the world. This disease is caused by Mycobacterium tuberculosis as well as several other Mycobacterium species, such as M. africanum, M. bovis, M. leprae, and a number of other species that belong to the group of Acid-Resistant Bacteria (BTA) (Rahma et al., 2024).

Mycobacterium tuberculosis is a Gram-positive intracellular pathogenic bacterium that spreads to the lungs through aerosol-based transmission. When a person with tuberculosis coughs or sneezes, about 3,000 bacteria can be released into the air in the form of microscopic sputum splashes called droplet nuclei. In individuals with strong immune systems, the bacteria that enter usually do not develop into disease, but rather remain in an inactive or latent state so that they do not cause symptoms and are not contagious. However, if the body's immune system weakens, the bacteria can become active again and cause active tuberculosis (Rahma et al., 2024).

According to the Global Tuberculosis Report 2021 issued by WHO, tuberculosis is still among the top ten leading causes of death in the world. To address these challenges, WHO developed the *End Tuberculosis* strategy as part of the achievement of *the Sustainable Development Goals* (SDGs), with the main focus being to end the global TB epidemic. The WHO Global TB Report for 2023 presents a comprehensive overview of the development of the TB epidemic and various efforts to prevent, detect, and handle it at the global, regional, and national levels. In the report, published on November 7, 2023, Indonesia remains in the group of two countries with the highest burden of TB cases in the world. Data from the Ministry of Health of the Republic of Indonesia as of November 3, 2023 recorded 658,543 cases of tuberculosis throughout Indonesia.

Indonesia needs to pay more serious attention to all legal and ethical aspects related to the protection of citizens who are participants in the TB vaccine clinical trials. On the other hand, pulmonary tuberculosis is a chronic infection caused by Mycobacterium tuberculosis, which is a pathogenic bacteria that attacks the parenchyma tissue of the lungs. The disease generally starts in the lungs before potentially spreading to other organs. The incubation period ranges from 2 to 10 weeks, after which the exposed individual may begin to show signs of health impairment, especially if his immune system is unable to respond adequately. Activation of the disease can last for a long period, characterized by an asymptomatic phase of remission that can progress to a phase of relapse. Mycobacterium tuberculosis itself is rod-shaped, Gram-positive, acid-resistant, and can be recognized through certain staining methods so that in microscopic examination it is classified as acid-resistant bacilli (BTA) (Nurhalisah et al., 2023).

Based on the descriptions that have been briefly presented above, tuberculosis cannot be underestimated. TB is a serious disease whose symptoms are often unnoticed or ignored by the general public. This is exacerbated by its very easy transmission process and is often underestimated. In this context, tuberculosis vaccination is indeed one of the most effective solutions to suppress the spread of the disease. The government and the state must seriously consider the principles of Human Rights (HAM) and the Right to Health in every policy related to the implementation of the vaccine trial.

Human rights are fundamental rights that everyone has wherever they are. Based on Law Number 39 of 1999, human rights are understood as a series of rights that are naturally inherent in every human being as a creature created by God Almighty. These rights are divine gifts that must be respected, maintained, and protected by the state, government, legal system, and all levels of society to maintain human dignity and dignity. The law also affirms that human rights have been owned by a person since he or she is born and must be respected by everyone, including those in authority. The protection of human rights must be based on legal principles that have moral legitimacy to safeguard human values, without being influenced by certain circumstances, political interests, or unilateral wishes of any party (Amalia et al., 2021). The foundation of human rights protection must be the main guideline in providing legal protection related to compensation, benefits, and risks for every individual who participates as the subject of TB vaccine trial research in Indonesia.

In the context of human rights classification, Indonesia divides human rights into two main categories, namely *non-derogable rights* and *derogable rights*. *Non-derogable rights* are fundamental rights that cannot be reduced or revoked under any circumstances and by any party, because these rights are absolute and permanently attached to each individual. In contrast, *derogable rights* are rights that can be limited or reduced by the state in certain situations, such as in emergencies or other extraordinary circumstances that have been regulated by law. Article 9 of Law Number 39 of 1999 concerning Human Rights states that everyone has the right to live, maintain their life, and improve their quality of life.

In addition, everyone is guaranteed the right to a healthy environment. The provisions regarding the right to obtain the highest degree of health are also affirmed in Article 4 paragraph (1) of Law Number 17 of 2023 concerning Health. Based on these principles, legal protection for the public participating as subjects in TB vaccine clinical trials must prioritize the aspects of compensation, potential benefits, and risks that may arise during the study.

The provisions contained in Article 4 paragraph (1) of the Health Law briefly state that everyone has the following rights.

a. Living a healthy life physically, mentally, and socially;
b. Obtain information and education about balanced and responsible health;
c. Getting safe, quality, and affordable health services in order to realize the highest degree of health;
d. Getting health care in accordance with health service standards;
e. Gain access to health resources;
f. Determine the health services necessary for themselves independently and responsibly;
g. Getting a healthy environment for the achievement of health degrees;
h. Accept or reject part or all of the relief measures to be given to him after receiving and fully understanding the information regarding such actions;
i. Obtain the confidentiality of his/her personal health data and information;
j. Obtain information about his/her health data, including actions and treatments that he has or will receive from medical personnel and/or health workers; and
k. Getting protection from health risks.

Article 4 paragraph (1) of the Health Law emphasizes the importance of health position, where in letter (a) it is emphasized that everyone has the right to live in good physical, mental, and social conditions. Every individual also has the right to obtain information and health education that can be accounted for, including information about the implementation of TB vaccine trials in Indonesia. This information includes compensation, benefits, and potential risks that may be received before and after a person participates as a research subject. If these rights are ignored, the implementation of TB vaccine trials in Indonesia has the potential to contain legal defects and can have adverse impacts on the life of the nation and state in the future.

However, the rights stipulated in letter (h) of the article may be waived. Article 4 paragraph (3) of the same law states that restrictions can be imposed on individuals suffering from infectious diseases with a high rate of spread, especially in the management of Extraordinary Events (KLB) or outbreaks, as well as on those who are not in a conscious state, are in an emergency, or have severe mental disorders. This provision, if not strictly supervised, has the potential to cause abuse, especially in the implementation of TB vaccine trials in the future.

On the other hand, the right to health as an integral part of human rights must be understood in a comprehensive framework, covering the social, economic, and political dimensions as a whole. The State has an obligation not only in terms of the provision of quality and affordable health services, but also in ensuring that all citizens, without exception or discrimination, can access these rights optimally. Therefore, the policy formulation process in the health sector must always be based on the principles of justice, ease of access, and sustainability in the implementation of health services (Fadhillah et al., 2025). Including those related to compensation, benefits, and risks for each party that is the subject of TB vaccine trial research.

Although the public has the right in principle to refuse to engage in vaccine trials, the provision does not apply to individuals suffering from tuberculosis. This is in line with Article

4 paragraph (3) of the 2023 Health Law, which limits the right to refuse under certain conditions. This situation shows that the interests of public health must be analyzed not only from a medical aspect, but also from a legal and ethical perspective. In this example, the interests of the wider community are placed in a more dominant position, although it seems to exclude ethical considerations because the individual concerned falls into the category as referred to in Article 4 paragraph (3). Prioritizing the interests of individuals in such conditions can actually be seen as contrary to legal and ethical principles that are built to maintain public safety.

Principles and Ethics of Health Research

Every research activity must be based on principles and ethics that ensure respect for human dignity. The advancement of science and the improvement of the quality of medical services are greatly influenced by the results of research conducted in this sector. Before an innovation can be implemented safely and benefiting humans, a testing process involving human participants needs to be taken. In practice, the research subjects often experience discomfort and face the possibility of various risks. Therefore, all potential risks—whether physical, social, economic, or psychological—must be described in a comprehensive and structured manner. Social risks, for example, can be in the form of stigma, discriminatory treatment, decreased appreciation from the surrounding environment, or even being the target of public ridicule (National Health Research and Development Ethics Committee of the Ministry of Health of the Republic of Indonesia, 2021).

The Helsinki Declaration is one of the most influential and widely used references for health research ethics around the world. This document is the main foothold for the implementation of medical research involving humans as participants. Since it was first enacted in 1964, the Helsinki Declaration has undergone a series of revisions by the World Medical Association through the General Assembly in an effort to adapt the principles of research ethics to the development of medical science and practice. To date, there have been eight revisions, namely in 1975 in Tokyo, 1983 in Venice, 1989 in Hong Kong, 1996 in Somerset West, 2000 in Edinburgh, 2002 in Washington, 2004 in Tokyo, 2008 in Seoul, and the last update in 2013 in Fortaleza, Brazil. Over time, this declaration has become the main reference in the development of various research ethics regulations at the global, regional, and national levels, as well as serving as a moral guideline for health workers conducting research involving humans (National Health Research and Development Ethics Committee of the Ministry of Health of the Republic of Indonesia, 2021).

In 2002, the Council for International Organizations of Medical Sciences (CIOMS), an international non-governmental organization officially affiliated with WHO, published an important document entitled The International Ethical Guidelines for Biomedical Research Involving Human Subjects. This guide contains 21 principles that govern various aspects of ethics in health research, particularly those related to biomedical research involving humans as subjects. CIOMS 2002 pays particular attention to the application of the principles in the Helsinki Declaration in developing countries, and was drafted with the aim of providing guidance in the formulation of policies and adjustments to ethical standards of health research to align with the social, cultural, and legal contexts applicable in each country (National Health Research and Development Ethics Committee of the Ministry of Health of the Republic of Indonesia, 2021). In this regard, Indonesia also needs to be guided by the regulations mentioned earlier, apart from the applicable laws and regulations in the health sector.

In the scope of research involving humans as subjects, the Helsinki Declaration has become an ethical reference that has been recognized globally. The moral values listed in the Declaration are then described in a more operational manner in the implementation guidelines known as *Good Clinical Practice* (GCP), or Good Clinical Trial Methods (CUKB). At present, GCP has become the primary standard in clinical trial execution. Consistently implementing GCP provides two key benefits: *first*, it guarantees that the data generated is valid and trustworthy; *Second*, ensuring optimal protection for the safety and welfare of the research subjects (National Health Research and Development Ethics Committee of the Ministry of Health of the Republic of Indonesia, 2021).

According to the provisions of the Helsinki Declaration, individuals or groups classified as vulnerable parties are seen as more likely to experience rights violations or receive additional adverse impacts when involved in a study. There are a variety of specific characteristics or conditions that can be used to determine whether a person belongs to the vulnerable group.

a. Ability to give consent

One of the widely recognized indicators of vulnerability is the limited ability of individuals to give conscious, voluntary, and free consent to their participation in a study.

b. Individuals in a hierarchical structure

Vulnerability can also arise in subordinative relationships, namely when prospective participants are in a position that is not completely free to make decisions independently. Examples of this situation include medical students, nurses, hospital staff, laboratory workers, employees at research sites, as well as members of the military or police.

c. Individuals who are in a closed institution

Residents of institutions such as nursing homes, mental hospitals, and correctional institutions are often classified as vulnerable groups, given the limited space they have and limited access to freedom that is generally enjoyed by the wider community (National Health Research and Development Ethics Committee of the Ministry of Health of the Republic of Indonesia, 2021).

Thus, researchers are required to have a deep understanding of ethical standards in research involving humans as subjects. They must master the content of the Helsinki Declaration, which provides guidance for researchers, scientists, and medical personnel in conducting health research with human participation, based on key ethical principles such as *respect for persons*, *beneficence*, and *justice* (National Health Research and Development Ethics Committee of the Ministry of Health of the Republic of Indonesia, 2021). The implementation of clinical trials involving vulnerable groups must be carried out through special procedures. This can be implemented by presenting independent witnesses, providing additional forms of protection through special assistance, and implementing other mechanisms designed to reduce the possibility of loss and risk to participants.

Awareness of the importance of protecting research subjects is also strengthened by UNESCO, a specialized agency of the United Nations that focuses on the economic, social, and educational fields. In 2005, UNESCO established a universal framework of principles and procedures in the field of bioethics containing 28 guidelines that are formulated in line with the general ethical principles of international application. Some of the main principles listed in the framework include respect for *human dignity and human rights*, a balance between benefits and *harms*, respect for autonomy *and individual responsibility*, and an emphasis on the importance of *consent* (National Health Research and Development Ethics Committee of the Ministry of Health of the Republic of Indonesia, 2021).

Independence and human rights are directly related to the right of every individual to accept or reject medical treatment, including in the context of TB vaccine trials in Indonesia. Clinical trial organizers are obliged to provide complete information about the form of compensation, potential benefits, and risks that may arise from involvement in the study. Each party involved in the implementation of the trial also bears the responsibility to ensure that the selection process of participants respects the autonomy of the prospective research subjects, including their right to decide whether or not to participate. This entire process must be closed by granting consent for participation that is legal, valid, and able to provide protection for the research subject. Therefore, the *informed consent* mechanism in the study must be carefully designed so that prospective participants have the capacity, understanding, and full freedom to make decisions regarding their involvement.

The ethical principles are also explicitly stated in Article 2 letter (f) of the Health Law. In his explanation, it was stated that what is meant by "ethical and professional principles" is that the provision of health services by medical personnel and health workers must be able to achieve and improve professionalism in practice, as well as uphold professional ethics and show a professional attitude. The same applies in the context of research ethics or clinical trials as stipulated in Article 188 paragraph (3) of the Health Law, which expressly raises issues surrounding the research. In his explanation, it is stated that, what is meant by "research-based services" is the services provided to patients as research subjects, especially in translational research that aims to prove the effectiveness of an intervention.

Furthermore, in the explanation of paragraph (4) of the same article, it is emphasized that what is meant by "responsible freedom" is the implementation of research that must be in accordance with scientific principles and based on ethics, moral values, religious norms, and laws and regulations. Thus, research that makes humans the subject of research or what is often referred to as "guinea pigs" must be carried out responsibly and must be based on the principles of ethics, morality, religious values, and applicable legal regulations. Including aspects of compensation, benefits, and risks that may arise for the research subjects in the TB vaccine trial.

Meanwhile, BPOM Regulation Number 8 of 2024 concerning the Implementation of Clinical Trial Approval also regulates ethical aspects in the implementation of clinical trials in Indonesia, which are relevant to be applied in the implementation of TB vaccine trials (Regulation of the Food and Drug Supervisory Agency Number 8 of 2024, 2024).. One of the important provisions in this regulation is the implementation of the Clinical Test Stage which is carried out after the Test Product has obtained a distribution permit and is officially marketed. Phase IV Clinical Trials are conducted taking into account the characteristics of the Test Product, and generally aim to conduct postmarketing safety monitoring as well as evaluate therapeutic effectiveness and treatment strategies. Although research methods at this stage may vary, their implementation is still mandatory to follow the same scientific standards and ethical principles as applied to the premarket clinical trial stage (Regulation of the Food and Drug Supervisory Agency Number 8 of 2024, 2024).. In addition, in another part of this regulation it is also emphasized that the implementation of clinical trials "... must pay attention to the safety aspects of the subject according to the ethics of the research." Furthermore, the place where the research is conducted is also required to be in accordance with the purpose and uphold the principles of research ethics.

Thus, principles and ethics in the implementation of health research in Indonesia must always be based on the principles of usefulness, transparent information disclosure, and respect for ethical, moral, religious, and oriental values that are the nation's identity. Each stage of research must also be carried out in accordance with the provisions of applicable laws and regulations, both at the national level and those that refer to international standards and regulations.

Legal Review of Clinical Trials

Vaccine trials or clinical trials in Indonesia must meet a certain number of requirements. The main requirement, as described in the previous section, is that its implementation must be guided by the principles of utility, uphold moral and religious values, be implemented transparently, and in accordance with the provisions of applicable laws and regulations. Vaccination is seen as one of the most effective approaches in preventing a wide range of serious diseases, including tuberculosis. The Indonesian people are expected to take part in the vaccination program as a preventive measure to reduce the risk of TB transmission.

However, problems arise when the vaccine to be given is still in the testing stage and is planned to be used in the general public. The implementation of the TB vaccine clinical trial raises concerns that it has the potential to interfere with the fulfillment of people's rights to obtain proper health services. This concern becomes even more relevant if the practice is accompanied by indirect pressure, as happened in the implementation of COVID-19 vaccination some time ago. Such subtle forms of pressure appear, for example, through the obligation to show a vaccine certificate as a condition of using public transport such as trains and planes, or to enter public facilities such as shopping malls. At that point, legal protection and justice enforcement efforts seem to have the potential to threaten the rights of people who choose not to participate in the vaccine trial.

Indonesia has also played an active role in the implementation of three clinical trials of candidate vaccines for tuberculosis. The first vaccine was developed through a collaboration between the Bill & Melinda Gates Foundation (BMGF) and British pharmaceutical company GSK, which uses a recombinant protein-based approach. The second vaccine is the result of a collaboration between a Chinese pharmaceutical company, CanSinoBio, and an Indonesian biopharmaceutical company, Etana, which utilizes viral vector technology and is currently in the first phase of clinical trials. Meanwhile, the third vaccine was developed by a German biotechnology company, BioNTech, in collaboration with an Indonesian pharmaceutical company, Biofarma, using mRNA technology and is currently in the process of finding a location for the implementation of the second phase of clinical trials in Indonesia. The three vaccines are scheduled to be completed in 2025 and are planned to begin widespread distribution in 2026 (Sari et al., 2024).

Vaccination efforts in developing countries such as Indonesia play an important role in reducing the incidence of TB infection. Although the effectiveness of the BCG vaccine is still a matter of debate in scientific circles, various studies show that vaccination remains one of the main strategies in the fight against tuberculosis until 2026 (Sari et al., 2024). However, the development of new anti-TB drugs is an urgent need to accelerate and simplify the treatment of drug-sensitive tuberculosis (TB SO), expand access to treatment for patients with drug-resistant tuberculosis (TB RO), and provide more effective therapeutic alternatives to treat latent tuberculosis infection (Sari et al., 2024).

On the other hand, the TB diagnosis and treatment process poses a considerable cost burden for affected families. The elimination of this financial burden is very important so that it does not become an obstacle in accessing TB diagnosis services and continuing TB treatment, so that the elimination target set by WHO can be achieved. The average direct medical expenditure to be borne by tuberculosis patients in low- to middle-income countries is estimated to be US$211 (with a 95% uncertainty interval between 154–302), while direct non-medical costs range around US$512 (428–620), and indirect costs of US$530 (423–663) for each episode of TB. Overall, the total cost to be borne by each patient amounted to about US$1253 (1127–1417). It is estimated that between 54% and 63.2% of families affected by TB experience an overall catastrophic cost burden. Therefore, the existence of national health insurance for the treatment of pulmonary tuberculosis is very important so that every individual can obtain proper health services without experiencing financial pressure or difficulties (Islamiyah et al., 2024).

In such situations and conditions, it is possible that people will ignore the right to health that they should have in order to gain access to the vaccine. Especially if the vaccination program is part of the policy of the government and the state in collaboration with foreign parties, which has the potential to use various forms of coercion so that people are willing to accept it, either voluntarily or under forced conditions. In this context, legal protection for the community seems to be vulnerable and as if it is in a threatened position.

Legal protection has one important dimension that is closely related to the principle of legal certainty. Legal protection can be classified into two categories, namely preventive protection and repressive protection. Preventive legal protection is a form of protection that prevents violations from the beginning. This protection provides an opportunity for the public to submit objections or inputs (*inspraak*) before a government decision is finalized. Thus, the main purpose of this legal protection is to prevent disputes, especially against government actions carried out based on the principle of discretion or freedom of action (Prayitno, 2017)..

With the existence of preventive legal protection, the government is encouraged to act more carefully in making decisions, especially related to the space for freedom of action (*freies ermessen*), while the public is given space to express objections or opinions on the decision plan to be taken (Prayitno, 2017). In today's digital era, the mechanism for submitting objections is often carried out through social media by viralizing government decisions or policies that are considered detrimental to the interests of the community, as a form of public participation and social control. On the other hand, the protection of repressive laws serves to resolve disputes that have occurred. In Indonesia, there are various institutions that play a role in providing legal protection for the public, which are generally divided into two main groups, namely courts within the scope of the General Judiciary and government agencies as administrative appeal institutions (Prayitno, 2017).

Meanwhile, broadly speaking, the process and requirements for conducting clinical trials begin with the obtaining of Clinical Trial Implementation Approval (PPUK). Based on Article 1 paragraph (10) of BPOM Regulation Number 8 of 2024 concerning Procedures for Approval of the Implementation of Clinical Trials, PPUK is a permit granted by the Head of the Agency to sponsors or contract research organizations responsible for carrying out clinical trials. In addition, every clinical trial activity must refer to the guidelines of Good Clinical Trial Practices (CUKB). Referring to Article 1 paragraph (9) of the same regulation, CUKB is a standard that regulates the process of designing, implementing, monitoring, quality assurance, auditing, recording, analysis, and reporting of clinical trials. This standard aims to ensure that the data and results obtained are accurate, accountable, and still guarantee the protection of the rights, integrity, and confidentiality of the research subjects.

After obtaining PPUK and fulfilling all the provisions stipulated in Good Clinical Trial Methods (CUKB), the next stage is to carry out clinical trials in accordance with the provisions of Article 1 paragraph (11) of BPOM Regulation Number 8 of 2024. In general, clinical trials are divided into two large groups, namely premarketing clinical trials and postmarketing clinical trials. Referring to Article 3 paragraph (2), premarketing clinical trials are carried out on Test Products that do not have a distribution permit in Indonesia, or on Test Products that have obtained a distribution permit but have undergone changes, for example related to indications, claims of efficacy or benefits, combinations of ingredients, or rules of use or dosology. On the other hand, Article 3 paragraph (3) explains that post-marketing clinical trials are intended for Test Products that have received distribution permits and aim to obtain additional information regarding safety aspects, or to reaffirm the efficacy and benefits that have been previously approved. Furthermore, Article 3 paragraph (4) emphasizes that the type of clinical trial as stipulated in Article 2 paragraph (4) letters a to e includes both premarketing and post-marketing clinical trials.

Post-marketing clinical trials, as stipulated in Article 2 paragraph (4) letters (a) to (e) of BPOM Regulation Number 8 of 2024, include various types of products such as drugs, natural ingredients, quasi-drugs, health supplements, and cosmetics. Meanwhile, the premarketing clinical trial refers to Article 2 paragraph (4) letter (f), which applies to processed food products. Based on these provisions, clinical trials or TB vaccine trials are included in the category of post-marketing clinical trials. Therefore, every clinical trial activity must obtain a Clinical Test Implementation Approval (PPUK) from BPOM first, in accordance with Article 6 paragraph (1), unless the clinical trial is carried out for educational purposes as stipulated in Article 6 paragraph (2). In addition, the implementation of clinical trials must be carried out at clinical trial centers as stipulated in Article 8. A clinical trial center, according to Article 1 paragraph (17), is a health service facility or other facility that is under the supervision of a health service facility used as a location for the implementation of clinical trials.

Based on this description, it can be concluded that the implementation of clinical trials or vaccine trials is strictly regulated with the main goal of providing legal protection for the community. However, it should be noted that the type of sanctions regulated in Article 32 of the BPOM Regulation of 2024 is only in the form of administrative sanctions. In addition, the violations regulated in the regulation generally still focus on the technical aspects of conducting clinical trials, and do not fully cover the potential losses that can be experienced by research subjects participating in clinical trials. Responsibility for the safety, protection of rights, and well-being of the individuals subject to clinical trials is vested in the Ethics Committee or an independent body. The body can be in the form of an assessment board or a committee that works at the institutional, regional, national, or international level. The membership consists of medical and non-medical personnel who have expertise and understanding in the field of research ethics (Regulation of the Food and Drug Supervisory Agency Number 8 of 2024, 2024).

D Protection of Vaccine Trial Research Subjects in Indonesia

A few months ago, Indonesia was again trusted as the location for an international vaccine clinical trial, this time for the M72/AS01E tuberculosis vaccine, which received funding of USD 550 million from the Bill & Melinda Gates Foundation. In the midst of the spotlight on the huge global philanthropic investment in this project, an important question to ponder is whether Indonesia's role will continue to be limited as a vaccine trial location for external interests, or whether the country will be able to develop its capacity to become a major actor in vaccine innovation and development at the global level. This question touches on the strategic dimension of national biotechnology independence, the role of the state in the global health agenda, and the need to strengthen research and development infrastructure based on national interests and scientific sovereignty (Djafri, 2025).

Vaccine trials and clinical trials basically have almost the same meaning. Both are used in the context of biomedical research involving humans as research subjects. This type of research is concerned with the medical and health aspects, which are ideally aimed at providing benefits to all of humanity. As the need to improve and develop health services increases, research involving humans is becoming increasingly important. Its main objectives include improving methods of diagnosis, therapy, and prevention, as well as deepening understanding of the causes and mechanisms of development of a disease. However, any biomedical research must adhere to the basic principles, namely respect for human dignity, protection of human rights and autonomy, and guarantees of the safety, health, and well-being of all research participants (Syahputra, 2018).

The general public in Indonesia generally does not have an adequate understanding of the trial process of a vaccine or other forms or medical measures. In fact, health is a fundamental and invaluable aspect of human life~~.~~ In Indonesia, there are still various public health problems that require serious attention from various stakeholders, considering their impact that directly affects the quality of human resources in the future. On the other hand, the increasing public expectations for optimal health services are often not in line with the readiness of medical personnel to meet these demands, thus causing various problems.

Therefore, strategic steps are needed that include planning to evaluation stages. One of the health issues that is very crucial and urgent to be addressed immediately is tuberculosis.

Patients suffering from pulmonary tuberculosis are required to undergo treatment for a relatively long period of time, which ranges from 6 to 9 months. As a result of this long duration of treatment, many cases are reported related to the patient's non-compliance in undergoing therapy, such as not taking medication regularly, stopping treatment in the middle of the process, feeling cured prematurely, or losing motivation to complete the entire series of treatments. This kind of unpreparedness, if left without adequate treatment and then used as a basis to make the Indonesian people the subject of TB vaccine trials, raises serious concerns about the aspect of legal protection for the community.

As an illusion, during the COVID-19 pandemic a few years ago, all levels of society were indirectly required to participate in the vaccination program. This is due to the fact that without proof of vaccination, daily social activities become very limited, especially for individuals who work in offices, use public transportation, or engage in shopping malls and other public facilities. Although there are exceptions for individuals with certain medical conditions, such as allergies or special illnesses, in general the vaccination policy at that time can be categorized as a form of covert coercion that is far from the legal protection and compensation that each individual deserves.

Especially when the vaccine to be applied is still in the trial stage and makes the entire people a testing arena or "guinea pig." In these conditions, the protection of law and justice is getting farther away. They tend to be able to only accept the vaccine with the simple thought that the vaccine is given for free, without being aware of the context of the compensation, benefits, and risks and understanding that the vaccination is part of the trial process on them. In this kind of phenomenon, legal protection for people who are required to participate in vaccine trials is highly dependent on the extent to which the obligations and prohibitions issued by the government are regulated fairly and transparently through government regulations themselves.

These situations and conditions are reinforced by the fact that various types of vaccines have been designed to prevent tuberculosis, such as the MVA85A vaccine combined with BCG to increase protection against this disease, as well as the M72/AS01E vaccine which has entered the phase three clinical trial stage. However, the results of a number of clinical trials show that the effectiveness of these vaccines still faces various limitations. Legal protection of research subjects is part of the responsibilities carried out by the Ethics Committee. However, when there is a violation or loss experienced by the research subject, the provisions regarding this are not explicitly included in the BPOM Regulation of 2024.

Meanwhile, the suitability of the implementation of clinical trials with ethical and legal standards must be optimally realized. The problem that arises is related to the compensation mechanism for research subjects who suffer losses due to their involvement in clinical trials. BPOM regulations do not provide an in-depth explanation of the form of compensation in question. The regulation only includes administrative sanctions that focus more on the technical aspects of implementation, by designating actors who ignore the obligation to provide compensation, benefits, and risks related to vaccine trials that are poorly understood by the general public.

The Health Research Ethics Committee (KEPK) must have a mechanism that ensures that the implementation of its duties is carried out in a transparent, accountable, consistent manner, and in accordance with high quality standards. Institutions that form KEPK are also obliged to implement a routine evaluation system on the performance of members and support staff, in order to ensure compliance with applicable written policies, regulations, and standard procedures. In addition, the ethical principles listed in international and national guidelines must always be the main reference and applied consistently and harmoniously in every stage of the research process.

Members of the Health Research Ethics Committee (KEPK) consist of individuals with special expertise, which includes clinicians, non-clinicians, as well as community representatives or lay individuals whose role is to provide perspective and input related to the interests of the research subject (Syahputra, 2018). With the composition of the membership, the implementation of evaluation, transparency, and accountability, as well as the involvement of control from civil society can be effectively realized. This is important considering that KEPK members are part of the community who are selected based on their respective competencies and integrity.

The absence of transparency, accountability, and adequate control will actually open up opportunities and increase the potential for violations of legal protection related to the right to information and legal consent. This is increasingly crucial considering that the Health Research Ethics Committee (KEPK) has at least three main roles, namely: *first*, protecting and supporting individual autonomy, both as candidates and research subjects; *second*, protecting the well-being of the candidate and the research subject; and *third*, balancing the various relevant moral considerations in the process of determining the research protocol, including respect for the autonomy, protection, and improvement of the subject's well-being (Syahputra, 2018).

E A Critical Review of Public Health Interests vs. Individual Protection

Human rights are divided into two main categories, namely *derogable rights* and *non-derogable rights*. Article 4 paragraph (2) of the International Covenant on Civil and Political Rights (ICCPR) classifies *non-derogable* rights into seven types, which include:

1. Right to life
2. The right to be free from torture
3. The right to be free from slavery
4. The right not to be detained due to failure to meet debt obligations
5. The right to be free from retroactive punishment
6. Right to be recognized as a subject of law
7. The right to freedom of thought, belief, and religion (Amalia et al., 2021).

The Constitution of Indonesia regulates provisions on *non-derogable rights* and *derogable rights* through Article 28I of the 1945 Constitution of the Republic of Indonesia. The article states that the right to life, the right to be free from torture, freedom of thought and conscience, freedom of religion, the right to be free from slavery, the right to be recognized as a person before the law, and the right to be free from retroactive laws are human rights that must not be diminished under any circumstances and circumstances. Thus, this provision confirms that these rights are included in the category of *non-derogable rights* (Amalia et al., 2021).

In addition, Article 28J of the 1945 Constitution of the Republic of Indonesia stipulates that restrictions on human rights can be enforced through law with the aim of ensuring respect and recognition of the rights and freedoms of others. The restrictions are also aimed at fulfilling fair demands based on moral considerations, religious values, and maintaining security and public order in a democratic society. Thus, this provision shows that Indonesia recognizes the existence of *derogable human rights* (Amalia et al., 2021).

Furthermore, based on the classification of human rights in Indonesia, these rights are divided into two main categories, namely *non-derogable rights* and *derogable rights*. The right to life is one of the rights that cannot be reduced, as affirmed in Article 28I of the 1945

Constitution which states that the right to life is a human right that must not be reduced under any circumstances. Therefore, the obligation to vaccinate can be seen as a form of fulfilling the state's responsibility for the protection of *these non-derogable* rights (Amalia et al., 2021).

Article 4 paragraph (1) letter (h) of the Health Law emphasizes that everyone has the right to accept or reject part or all of the medical procedures to be given, after obtaining and understanding complete information about the action. This provision shows the protection of individual interests and autonomy. However, this right is not absolute. Article 4 paragraph (3) of the same law states that the right to refuse medical action can be waived under certain conditions, including when a person suffers from a rapidly transmitted disease, is in a situation of dealing with an Extraordinary Event (KLB) or outbreak, is unconscious, facing an emergency situation, or experiences severe mental disorders in an emergency situation.

At that point, the individual's rights become limited because he is obliged to accept all forms of treatment and medical measures given due to the condition he is experiencing. This is caused by an emergency situation that has the potential to endanger the general public around it. On the other hand, if the individual does not suffer from a dangerous infectious disease, then the rights and legal protection in Article 4 paragraph (1) letter (h) remain inherent and cannot be reduced. Therefore, this provision shows characteristics as *a non-derogable right*, when viewed in the context of the exceptions stipulated in Article 4 paragraph (3) of the Health Law.

Article 4 paragraph (3) of the Health Law above shows the existence of an element of *derogable right*, because in certain circumstances the public interest is placed above individual rights as stipulated in Article 4 paragraph (1) letter (h). In an emergency situation that a person experiences, he cannot refuse medical measures or countermeasures that have been set. The consent given in such a situation is imperative, as it arises from a compelling external circumstance. In other words, *informed consent* in this context occurs not solely because of voluntariness, but because of an urgent need that requires a deviation from the autonomy of the individual. In such situations, ethical principles appear to be set aside, but the exception is legally justified because it aims to protect the public interest.

However, it is not uncommon for clinical trials conducted with the aim of good to actually experience deviations and violations of ethical principles. One of the most striking examples of ethical violations in the field of medical research occurred during the Nazi regime (*Nationalsozialismus*) in Germany. In the period between 1940 and 1945, unethical studies were conducted on prisoners of war at the Auschwitz concentration camp in Poland, where individuals were subjected to experiments without consent and in inhumane conditions.

In the period from 1950 to 1960, the United States once carried out a secret project known as MKULTRA, namely the Mind Control Program run by the *Central Intelligence Agency* (CIA). This program is an illegal activity and is carried out behind closed doors, in which the CIA conducts experiments on humans without legitimate consent. The main objective of the research is to discover and develop various chemical substances and certain methods that can be used in the interrogation process, including torture, in order to control or weaken the mental state of individuals through systematic manipulation of the mind.

Referring to various cases of ethical violations in biomedical research that have occurred, a number of specific ethical guidelines in the field of medicine and biomedicine were born. Every research that involves humans as subjects must be based on three main principles, namely respect for the individual, the principle of *beneficence*, and justice. Adhering to these principles, any research involving humans must be prepared through careful planning, oriented towards providing maximum benefits, and reducing the risk and possibility of errors. Individuals who are the subject of research must be treated with respect and fairness according to applicable moral values. Research should not be based on the personal interests of researchers or institutions, but must prioritize the interests of the subject and make a real contribution to the development of science, reducing suffering, or improving the quality and expectation of human life.

Meanwhile, in the context of the TB vaccine trial in India, it should be noted that India is the country with the highest burden of TB (TB) in the world, although the rate of spread shows significant variation between regions. Based on the National TB Prevalence Survey conducted in the period 2019 to 2021, the prevalence of TB nationally is estimated to reach 312 cases per 100,000 population for all age groups.

The report of the vaccine trial in India shows the range of costs required at the time, and shows how the implementation of the trial is differentiated by service area, i.e. between rural and urban areas. Meanwhile, in Indonesia, health facility services in rural areas and remote areas generally still face challenges in the form of long distances, limited capabilities of health workers, and lack of supporting facilities and infrastructure. In the Indian context, the government divides the vaccine trial area between New Delhi and Gujarat, and based on the available reports, the implementation of vaccine trials in both regions is considered to be successful.

Findings in a vaccine trial study in India confirm the importance of conducting a broader survey to accurately measure the prevalence of infection. The study highlights the urgency of modeling infection prevalence at the regional level as a basis for estimating the impact of vaccination, particularly if vaccine effectiveness depends on infection status—whether the individual has been infected or not. Estimating the prevalence of infection by age in each region will be very useful in designing vaccination strategies that are adjusted to the status of infection, as well as improving the accuracy in projecting the impact of vaccines.

However, it is not appropriate for a country, including Indonesia, to immediately approve vaccine trials on its citizens. The implementation of TB vaccine trials needs to be aligned with the provisions of the health law applicable in Indonesia, taking into account the various eastern values, norms, morals, religions, and traditions in each region in Indonesia. The main challenges in Indonesia in the implementation of clinical trials, including TB vaccine trials, are low public health literacy and limited health service facilities in remote areas. This condition can hinder the public's understanding of their rights and obligations as clinical trial subjects.

In addition, it is necessary to conduct critical reflection on the practice of vaccine trials in Indonesia. Dependence on external funding without being balanced with strengthening domestic research capacity has the potential to cause inequality in power relations between donor countries and recipient countries. Therefore, Indonesia needs to strengthen its biomedical sovereignty, including in the aspect of supervision and regulation of health research, so that it does not just become an object of experiments. In the context of the ongoing TB vaccine trials, the state has a constitutional responsibility to ensure that all research not only meets scientific standards, but is also carried out in accordance with ethical, legal, and social values. This is important to ensure maximum protection of the rights and dignity of every citizen.

CONCLUSION

The implementation of TB vaccine clinical trials in Indonesia must adhere to national health law provisions, prioritizing principles of utility, moral and religious values, and prevailing eastern norms while ensuring full compliance with relevant regulations; public health interests may justify limiting individual rights—such as those under Article 4 paragraph (1) letter (h) of the Health Law—when strong evidence indicates rapid spread of infectious diseases. To enhance legal protection for research subjects, the government should promptly update regulations with stricter criminal sanctions for violations and promote broader public participation across all trial stages to minimize miscommunication, foster informed consent, and uphold subjects' rights fairly. For future research, scholars could empirically investigate the effectiveness of public engagement mechanisms in real-world TB vaccine trials through comparative case studies across Southeast Asian countries, identifying best practices for balancing legal safeguards with accelerated public health responses.

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