

# THE ETHICAL PARADOX OF INFORMED CONSENT IN HPV VACCINATION: EXAMINING THE LEGAL BOUNDARIES AND ETHICAL CONSIDERATIONS OF PARENTAL CONSENT, PUBLIC HEALTH, AND INDIVIDUAL RIGHTS

## ABSTRACT

**Background and Objective:** Effective communication is essential in medical procedures, and informed consent is a key example of this. However, informed consent may encounter unique circumstances, such as in life support situations or government health programs. The Human Papillomavirus (HPV) vaccination, part of a government initiative, raises questions about whether informed consent is still required. Patients may choose to reject medical actions, so it is crucial to understand the legal implications of refusing the HPV vaccination. This study aims to examine whether informed consent is still necessary for the HPV vaccination and to analyze the legal consequences if a citizen refuses to receive it. **Method:** This study adopts a normative juridical approach with an analytic descriptive specification. Secondary data was gathered from primary, secondary, and tertiary legal sources through literature reviews, document studies, and archival research. The collected data was then analyzed qualitatively and presented in a descriptive format. **Results:** The study found that there are exceptions to the requirement for informed consent for vaccinations included in government programs. Specifically, informed consent is not necessary for individuals within the target age group of the government's HPV vaccination program. In Indonesia, this program targets girls aged 9 to 14. Additionally, there are currently no legal penalties for individuals who refuse the HPV vaccination. **Conclusion:** Informed consent is not required for individuals within the targeted age group of the government's HPV vaccination program in Indonesia. Furthermore, there are no legal penalties for rejecting the vaccination.

**Keywords:** Legal ethic, Informed consent, Human Papilloma Virus vaccination. Government program

## 1. INTRODUCTION

In medical practice, effective communication between medical personnel and patients is essential. Communication between doctors and patients should be based on mutual trust, both during the examination and treatment process as well as during the patient's recovery process, to foster a good interpersonal relationship[1]

This communication includes providing the patient with information about their health condition, the steps of the examination to be conducted, and the treatment measures that will be undertaken. Once the information has been communicated, the patient can give their consent or refusal for any procedure to be performed on them.[2]

This study aims to understand the role of informed consent in special situations, such as in life-support scenarios and government programs. According to Article 15 of the Indonesian Ministry of Health Regulation Number 290 of 2008 on Informed Consent, it is stated that "In cases where medical procedures must be carried out as part of a government program intended for the greater public interest, informed consent is not required [3]

In Indonesia, cervical cancer ranks as the second most common cancer, with 36,633 cases or 9.2% of the total cancer cases in the country[4][5] This high incidence has prompted the Indonesian Ministry of Health (Kemenkes RI) to support the acceleration of cervical cancer elimination through the National Action Plan (RAN). The RAN for Cervical Cancer Elimination consists of four pillars: [6]Pillar 1: Service Delivery (This includes vaccination, screening, and management) ; Pillar 2: Education, Training, and Outreach (Focused on strengthening healthcare professionals and increasing public awareness) ; Pillar 3: Progress Drivers (Encompassing activities such as monitoring, evaluation, research, and digital support) ; Pillar 4: Management and Organization (Involving governance and policy formulation, funding for elimination efforts, and cross-sectoral collaboration and partnerships).[7]

Vaccination is considered a medical procedure, and in accordance with Article 45 of Law Number 29 of 2004 concerning Medical Practice, informed consent must generally be obtained.[8] However, in specific situations such as vaccinations implemented under government programs, informed consent is not required, as stated in the Indonesian Minister of Health Regulation Number 290 of 2008. Therefore, it is essential to review the significance of informed consent in special situations like the human papillomavirus (HPV) vaccination, which is part of a government program.[9]

In the therapeutic relationship between doctors and patients, medical procedures, including vaccinations, may face refusal. If there is a refusal to receive a vaccination under a government program, what are the potential legal consequences for the patient? Additionally, could the medical professionals involved with the patient who refuses vaccination also face legal implications? Considering that informed consent is required to protect healthcare providers from liability for negligence or omissions. [10] Thus, this study aims to examine the legal consequences for both patients and healthcare providers when there is a refusal to receive vaccination as part of a government program. It emphasizes the need for an ethicolegal review of informed consent in the context of human papillomavirus (HPV) vaccination.[11]

This study aims to understand the role of informed consent in special situations, such as in life-support scenarios and government programs, specifically in the context of the Human Papillomavirus (HPV) vaccination, which is part of a government program. The study also aims to analyze whether informed consent is required for HPV vaccination within the framework of a government program and to assess the legal consequences that may arise if a patient refuses the HPV vaccination. Additionally, this research seeks to explore the potential legal implications for both patients who refuse vaccination and medical professionals involved in the vaccination process, considering the need for legal protection for healthcare providers against liability for negligence or omissions. The study emphasizes the importance of an ethicolegal review of informed consent in the context of the HPV vaccination within a government program in Indonesia

## **2. METHODS**

The approach method used in this study is normative juridical. Normative legal research essentially examines the law as a concept of norms or rules that apply within society and serve as a reference for individual behavior[12]The research specification used is descriptive-analytical. Descriptive research illustrates the frequency of legal phenomena or events, the characteristics of legal phenomena, or the frequency of relationships between one legal phenomenon or event and another. Analytical research aims to understand the conceptual meaning contained in terms used in legislation while also examining their application in practice and legal decisions.. [13]. The type of research design used is a descriptive design, which is conducted to answer questions about who, what, when, where, and how, in relation to a specific study. Descriptive research is utilized to gather information about a phenomenon, variable, or situational condition.[14]. This study involves two variables: independent and dependent variables. The independent variable in this research is informed consent for medical procedures in accordance with Indonesian legal regulations. The dependent variable is the implementation of informed consent in the context of human papillomavirus (HPV) vaccination..This study relies solely on secondary data, which is data obtained from existing sources. Secondary data is collected through literature reviews and can be categorized into primary legal materials, secondary legal materials, and tertiary legal materials or other related resources. In normative legal research, there are three methods for collecting secondary data: literature studies, document analysis, and archival studies. The data gathered will be presented in a systematically structured narrative. The data analysis technique used in this research is qualitative analysis, which emphasizes a deeper understanding of the issues rather than aiming for generalization of findings. [15]

### **3. RESULT**

Health is one of the basic human needs. In 2000, through the Second Amendment to the 1945 Constitution, health was affirmed as part of human rights. [16]This is stated in Article 28H, paragraph (1): "Everyone has the right to live a prosperous life, both physically and mentally, to have a place to live, and to receive a good and healthy environment, as well as the right to obtain health services." The right to health as a human right has been recognized and regulated in various international and national instruments. Nationally, the right to health as a human right is emphasized in several laws, including Law No. 39 of 1999 concerning Human Rights, Article 9, paragraph (3): "Everyone has the right to a good and healthy environment." [17]

In the explanation of Law No. 36 of 2009 concerning Health, it is stated that health is a human right and one of the elements of well-being that must be realized in accordance with the ideals of the Indonesian nation as outlined in the Pancasila and the Preamble to the 1945 Constitution of the Republic of Indonesia. In Article 4 of Law No. 36 of 2009, it is stated, "Everyone has the right to health." Article 5, paragraph (2) of Law No. 36 of 2009 mentions, "Everyone has the right to obtain safe, quality, and affordable health services." Article 17 of Law No. 36 of 2009 states, "The government is responsible for ensuring access to information, education, and health service facilities to improve and maintain the highest possible level of health." [18]

Achieving a high level of health is closely tied to medical interventions. For every medical procedure, informed consent is essential, starting from the therapeutic transaction and throughout the doctor-patient relationship. According to the Ministry of Health Regulation No. 290/MENKES/PER/III/2008 concerning Informed Consent for Medical Actions, all medical procedures performed on patients must obtain consent (informed consent), whether written or

verbal. This consent must include explanations covering the diagnosis, the method of the procedure, the purpose of the action, alternative treatments, risks and complications, prognosis, and estimated costs. Consent is given after the patient has received an explanation of the action to be taken.[19]

According to the Minister of Health of the Republic of Indonesia Decree No. HK.01.07/MENKES/1930/2022 regarding the Human Papillomavirus (HPV) Vaccine Introduction Program for 2022-2023, achieving the global target of cervical cancer elimination by 2030 requires accelerated efforts to provide HPV immunization for girls, with a minimum coverage target of 90%. The government has established the HPV vaccination introduction program for 2022-2023, which is implemented in all districts/cities across Indonesia since 2023. This program is conducted as part of the national immunization program and integrated with the School Immunization Month (BIAS) activities, targeting school-age girls in primary and equivalent madrasah levels. The HPV vaccination, which is a government program, is carried out without requiring informed consent from the target population. However, vaccination against HPV for high-risk groups is still recommended and not included in current Minister of Health regulations or the official vaccination program.[20] So far, there have been no administrative sanctions imposed by the government on individuals who refuse the HPV vaccination. The current Minister of Health's decree stipulates that all girls aged 9-14 years are entitled to receive the HPV vaccine for free through the government's program. However, there has not been a developed implementation plan to reach girls in this age group who are out of school or those in high-risk communities for HPV infection. This has resulted in a gap between policy and the actual implementation of the HPV vaccination program itself.. [20] For healthcare workers administering vaccinations as part of the government program according to the target outlined in the Minister of Health's Decree No. HK.01.07/MENKES/1930/2022, they cannot be subject to criminal sanctions for performing their official duties. This is in accordance with Article 51 of the Indonesian [21] Criminal Code (KUHP), which states: "(1) Anyone who commits an act to carry out an official order given by an authorized authority shall not be criminally charged."

#### **4. DISCUSSION**

HPV vaccination is recommended to prevent new HPV infections and diseases associated with HPV, including several types of cancer. HPV vaccination, along with surveillance and screening strategies, is a key public health measure to prevent cancers caused by HPV. The goal of the HPV immunization program is to reduce the morbidity and mortality of HPV-related diseases that are still preventable. The objective is to lower the cervical cancer incidence to 4 per 100,000 people per year by 2030, with the primary target group being girls aged 9-14 years. Based on the Minister of Health of the Republic of Indonesia Decree No. HK.01.07/MENKES/1930/2022 regarding the introduction of the Human Papillomavirus (HPV) Vaccine Immunization program for 2022-2023, it states that to achieve the global target of cervical cancer elimination by 2030, efforts must be made to accelerate the administration of the HPV vaccine to girls, with a minimum coverage of 90%. The government has established the HPV Vaccine Immunization Introduction Program for 2022-2023, which will be implemented across all districts/cities in Indonesia starting from 2023. This program will be conducted as part of the school-based immunization program (Bulan Imunisasi Anak Sekolah, BIAS) and targets girls of elementary school/Madrasah Ibtidaiyah age and their equivalents.. Ethically, informed consent is required to fulfill the principle of autonomy. However, in the case of the HPV vaccination, which is part of a government program, the vaccination is administered to the target group without requiring informed consent. On the other hand, for groups

at higher risk of HPV infection, the HPV vaccination is still recommended but is not yet included in the Ministry of Health's regulations or the vaccination program. Therefore, from an ethical perspective, informed consent is necessary to uphold the principle of autonomy for those at risk (outside of the target group for the government's HPV vaccination program)..

Currently, there are no administrative sanctions imposed by the government on individuals who refuse the HPV vaccination. For healthcare workers who administer the vaccination as part of the government's program according to the target set forth in the Minister of Health of the Republic of Indonesia Decree number HK.01.07/MENKES/1930/2022, they cannot be subject to criminal sanctions when carrying out the mandated duties of their position..[22]

## **CONCLUSION**

Based on Minister of Health Regulation (PMK) Number 290/MENKES/PER/III/2008 regarding Medical Action Consent, all medical procedures performed on patients must obtain consent (informed consent), either written or oral.[23] According to the Decree of the Minister of Health of the Republic of Indonesia Number HK.01.07/MENKES/1930/2022 concerning the introduction of the Human Papillomavirus (HPV) Vaccine program for 2022-2023,[20] it is stated that, in order to achieve the global target of eliminating cervical cancer by 2030, efforts to accelerate the administration of the HPV vaccine to girls with a minimum coverage of 90 percent are required. Therefore, the government has established the introduction of the HPV vaccination program for 2022-2023, which will be implemented in all regencies and cities across Indonesia starting in 2023. With the issuance of the Decree, the vaccination program is integrated with the School Immunization Month (BIAS) activities, targeting girls of elementary/madrasah ibtidaiyah school age and equivalent. Ethically, informed consent is required to uphold the principle of autonomy. However, in the case of the HPV vaccination, which is part of the government program, the vaccination is administered to the target group without obtaining informed consent. Meanwhile, for individuals at risk of HPV infection, the HPV vaccination is still recommended but is not yet included in the Minister of Health's regulations or the official vaccination program. Therefore, ethically, informed consent is necessary for at-risk groups (those outside the government program's target group for HPV vaccination) to uphold the principle of autonomy.

The government seeks to protect the well-being of the community in the health sector by recommending and establishing the HPV vaccination program. This represents a form of preventive legal protection. However, there is a gap between policy and the implementation of the HPV vaccination program itself, as there are currently no administrative sanctions for individuals who refuse the HPV vaccination.[24] Furthermore, there is no developed implementation plan to reach at-risk groups outside the target population outlined in the Ministerial Decree, such as girls who have dropped out of school or high-risk communities for HPV infection. Therefore, the provision of information about the HPV vaccination needs to be further enhanced, so that the public can have an accurate understanding of the matter. [25]

## **DISCLAIMER (ARTIFICIAL INTELLIGENCE)**

The authors hereby state that no generative AI tools such as large language models (ChatGPT, COPILOT, etc.) or text-to-image generators were utilized in the creation or editing of this work.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

## DATA AVAILABILITY

All relevant data are included in the paper and its supporting information files. This study will assist researchers in identifying critical areas for The Ethical Paradox Of Informed Consent In Hpv Vaccination: Examining The Legal Boundaries And Ethical Considerations Of Parental Consent, Public Health, And Individual Rights.

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