

Implementation of Immunization Program: Does it Need Informed Consent?

Rani Tiyas Budiyanthi^{1, *}, Ayun Sriatmi², Nikie Astorina Yunita Dewanti³

^{1,2}Health Policy and Administration, Faculty of Public Health, Diponegoro University, Indonesia

³Faculty of Public Health, Diponegoro University, Indonesia

Abstract

Immunization program is important to prevent children from getting diseases that can be prevented by immunization. However, in the implementation of this program there were some controversies and rejections related to adverse events following immunization (AEFI), belief, and halal factor. This study aims to determine whether informed consent regarding immunization programs needs to be done considering the importance of immunization for children's health. This research is a normative research with statue and comparative approach. The data comes from law, journal, proceedings, and articles about health law. In many countries, informed consent was needed in immunization program. But there is, any exception according to belief, philosophy, culture, and religion. In Indonesia, implementation of government program not needs informed consent. But it is not consistent with other regulation about implementation of immunization program. Indonesia needs to review the regulations regarding immunization and synchronize between regulations, so that in the implementation there are no conflicting regulations and overlapping with each other.

Keywords: Immunization program, Disease, Rejections, AEFI, health, Implementation.

***Author for Correspondence** E-mail: ranitiyasbudiyanthi@gmail.com

BACKGROUNDS

Immunization program is a health service program that was promoted by the government. The program is effective to prevent diseases that can be prevented by immunization. In 1972, there was a decrease in the number of smallpox in Indonesia and in 1985, there was a marked decline in several infectious diseases especially for diseases diphtheria, tetanus, pertussis, measles, and polio [1]. However, in immunization there is a possibility of side effects called adverse events following immunization (AEFI) from local and systemic side effects that can be life threatening [2].

In addition, some rejections in the immunization program are motivated because belief factors such as the immune system can fight the disease without immunization [3]. Some beliefs also mention that halal vaccines used in immunization are still questionable [4]. This is of course influential in achieving an immunization program organized by the government. The spread of these issues is reinforced by the development of information technology which has contributed to the spread

of anti-vaccine thinking through blogs, web, instant messaging and social media [5]. No exception, hoaxes about vaccination also spread easily. It can make the infection disease spread easily if immunization coverage is low.

In the global context, the anti-vaccination movement has a long history. According to Heidi J Larson, a PhD from the London School of Hygiene and Tropical Medicine, said that the anti-vaccine movement was first formed in 1866 known as the anti-compulsory vaccination league, the movement that refused the smallpox vaccine. But in the 20th century, smallpox caused 300 to 500 million casualties [6]. The World Health Organization (WHO) then stated that smallpox was a disease that was successfully completed by immunization since 1980 and then began a global immunization campaign by WHO. The campaign paid off, since 1988 the number of polio cases has decreased by 99% worldwide except Afghanistan, Nigeria and Pakistan [6].

Vaccination in cases of diphtheria also experienced controversy in the past. In the mid-1970s, the safety of the Diphtheria

Pertussis Tetanus (DPT) vaccine was discussed in Europe, Asia, Australia and North America [7]. Even in Britain, the opposition has alleged that as many as 36 children treated at Great Ormond Street Hospital suffered neurological disorders after receiving DPT immunization [7]. Television and newspapers also raised the controversy so that the problem became more widespread. Plus an advocacy group, the Association of Parents of Children Who Refuse Vaccines (APVDC) also disseminates their views on the risks and consequences of the DPT. The controversy caused a significant reduction in vaccination rates and increased epidemic of three diseases, especially whooping cough (pertussis).

Diphtheria is an epidemic in Indonesia. In 2017, the Ministry of Health has even determined diphtheria in the status of Extraordinary Events (KLB). This is because deadly diseases caused by the *Corynebacterium diphtheria* bacteria caused dozens of casualties in 20 provinces. Until November 2017, there were 95 districts from 20 provinces that reported cases of diphtheria with a total of 622 cases and 32 of them died. Diphtheria is actually an old disease that was almost non-existent in the 1990s, but began to spread again in 2009 [8]. The disease can be prevented by DPT vaccines and included in immunization-preventable diseases (PD3I). According to the Minister of Health Regulation Number 1501 year 2010 on Certain Types of Infectious Diseases, if one case of clinical diphtheria is found then it has entered into Extraordinary Events [9].

The pros and cons in vaccination are a problem when the government implements immunization as a health prevention program that must be given to all children. The question that arises later is whether informed consent or parental consent is needed for an immunization program?

METHODS

This research is normative research with statue and comparative approach. The primary data comes from law jurisdiction in Indonesia. Secondary data comes from journal, proceedings, and articles about health law. Other source comes from journal, proceedings, and articles about health and bioethics.

RESULTS AND DISCUSSION

Informed Consent of Immunization Program

Informed consent is an agreement to a therapeutic action that was given after the patient or his parents (in case of child patient) receive adequate information. There are several conditions for someone who can give informed consent i.e. adults (aged 18 years or more), competent, capable, and the object of the agreement is lawful [10].

Vaccination is mandatory for school-age children in the United States, but health policy makers are increasingly concerned about the choice of parents to choose exclusion from vaccination requirements. Currently exceptions to vaccination tend to be allowed for medical reasons in all countries, due to religious reasons in 48 countries and philosophical factors in 20 countries [11, 12]. Data was obtained that approximately 1–3% of children who did not get vaccinated because of the weld [11]. However, it was found that even though the vaccination refusal rate was quite low, the rate of outbreaks in schools increased by 2–4%. As for example what happened in southern Pennsylvania, health workers find it difficult because the spread of infectious diseases causes increased morbidity and mortality as many parents refuse to immunize their children [11].

Based on Article 15 Ministry of Health Regulation in Indonesia Number 290 year 2008 on Informed Consent, implementation of government program not need informed consent [13]. But, it is not consistent with other regulation about implementation of immunization program. According to Article 32 point 3 Ministry of Health Regulation in Indonesia Number 12 year 2017, approval of immunization is marked by the arrival of the patient / child to the place of immunization [14]. Other regulation, Article 26 *ayat* (2) Ministry of Health Regulation in Indonesia Number 12 year 2017 states government vaccines are not given in the condition that parents reject the vaccine from the government [14].

This condition shows that government's inconsistency regulation regarding immunization. If the approval of the

immunization program is marked by the arrival of patients at the place of immunization, that's mean immunization still requires approval from the patient and the government cannot force patients.

The government also cannot carry out immunization movements by visiting people who have not been immunized. Other regulatory inconsistencies are also found in the Article 33 Ministry of Health Regulation in Indonesia Number 12 year 2017 on Implementation Immunization Program which states that all of people who inhibit the implementation of immunization programs are can be subject to sanctions. This condition raises the question whether parents who do not agree that their children being immunized can be sanctioned?

Ethical Aspect of Informed Consent in Immunization Program

When an immunization program becomes an obligation, there is a situation where patient autonomy is faced with public health regulations and policies. So, in this case there are two things that must be considered. The first is patient autonomy, second is the guarantee of public health and the implementation of the public health policy.

Ideally, when information about the importance of vaccination is given to parents, parents will give voluntary approval in signing the form so that vaccination can be done. However, with the anti-vaccine movement, parents' reluctance, and epidemic outbreaks that have occurred forced each country to require immunization.

Although vaccination has become a program, but in its implementation, informed consent was needed. This is because in the implementation of vaccination there is still a possibility of occurrence of adverse events following immunization (AEFI). In the approval of a medical act, parents are required to be voluntary. This is also not very meaningful because the rejection also has implications in law.

In addition, in some countries and regions immunization also affects obligations in other

policies. In America for example, children who do not get vaccinations are not permitted in public schools [15]. In Poland, families who reject vaccinated children will be subject to sanctions [16]. In terms of obligations that must be carried out, voluntary or the principle of patient autonomy becomes an overlooked thing. Patients become obliged to carry out immunization programs and sign the willingness to vaccinate.

In the end, the government can't force the people. Government can conduct public education in the form of distributing information about immunization, conducting immunization campaigns, using information technology to distribute health information about the importance of immunization. In addition, the government can also implement a reminder strategy for immunization through social media, print media, and electronic media. In order for the immunization program to be carried out properly, government support is needed such as providing free vaccines for patients, giving gift certificates, providing public places and private places for vaccinations, home visits, and other health service support.

CONCLUSION

Informed consent in immunization program was needed although the immunization program being obligation in health sector. Another approach was needed to make the program be successful such as public education, reminder strategy, home visit, and free vaccinations. Synchronize regulation in the country also needed so that in the implementation not conflicting and overlapping with each other.

REFERENCES

1. Ministry of Health in Indonesia. Ministry of Health Decree Number 1059 year 2004 on Guideline for Implementation of Immunization Program.
2. World Health Organization. Adverse Events Following Immunization (AEFI). Available from: https://www.who.int/vaccine_safety/initiative/detection/AEFI/en/
3. Smith CT. Vaccine Rejection and Hesitancy: A Review and Call to Action. *Open Forum Infect Dis.* 2017; (4): 3.

4. Ahmed Ali, et al. Outbreak of vaccine-preventable disease in Muslim majority countries. *Journal of Infection and Public Health*. 2018 (11) 2: 153–155.
5. Evrony, A and Caplan, A. The overlooked dangers of anti-vaccination groups' social media presence. *Hum Vaccin Immunother*. 2017; 13 (6): 1475–1476.
6. Gander K. UK. The rise of the anti-vaccine movement and what it means for public health. 2017. Available from: <https://www.vaccineconfidence.org/uk-the-rise-of-the-anti-vaccine-movement-and-what-it-means-for-public-health/>
7. Kulenkampff M, Schwartzman JS, Wilson J. Neurological complications of pertussis inoculation. *Arch Dis Child*. 1974; 49:46–49.
8. Ministry of Health in Indonesia. Outbreak Diphtheria, Dangerous, and Can be Prevented with Immunization. 2017. Available from: <http://www.depkes.go.id/article/view/17121200002/menkes-difteri-menular-berbahaya-dan-mematikan-namun-bisa-dicegah-dengan-imunisasi.html>
9. Minister of Health Regulation Number 1501 year 2010 on Certain Types of Infectious Diseases.
10. Rao KHS. Informed Consent: An Ethical Obligation or Legal Compulsion? *J Cutan Aestht Surg*. 2008; 1 (1):33–35.
11. Sharts-Hopko. Issues in pediatric immunization. *MCN Am J Matern Child Nurs*. 2009;34(2):80–88.
12. National Conference of State Legislatures States with religious and philosophical exemption from school immunization requirements. Available from: www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx.
13. Ministry of Health Regulation in Indonesia Number 290 year 2008 on Informed Consent.
14. Ministry of Health Regulation in Indonesia Number 12 year 2017 on Implementation Immunization Program.
15. Hendri KS, et al. Ethics and Childhood Vaccination Policy in the United States. *Am J Public Health*. 2016; 106 (2): 273–278.
16. Patryn RK, Zagaja A. Vaccinations-Between free will and coercion. *Human Vaccines and Immunotherapeutic*. 2016. 12 (8): 2204–2205.

Cite this Article

Rani Tiyas Budiayanti, Ayun Sriatmi, Nikie Astorina Yunita Dewanti. Implementation of Immunization Program: Does it Need Informed Consent?. *Indian Journal of Health and Medical Law*. April 2018; 1(2): 51–54p.