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Implementation of Policy Regulation on Dengue Fever Treatment Through Gene Drive of Wolbachia Bacteria

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Abstract: Dengue fever is an infectious disease transmitted through the bite of the Aedes aegypti mosquito. Efforts to control this disease often face insecticide resistance and environmental factors. One innovation that is expected to reduce the spread of DHF is the application of gene drive by utilizing Wolbachia bacteria. This technology works by infecting mosquito populations to reduce their ability to transmit dengue virus. This article discusses the implementation of the policy on dengue treatment through gene drive based on Wolbachia bacteria in Indonesia, focusing on regulatory aspects, field tests, and community acceptance of the technology. This study used a qualitative approach with secondary data analysis from policy documents, field trial results, and interviews with stakeholders. The results showed that although field trials showed promising results in reducing the spread of DHF, the challenges faced were immature regulations and public concerns regarding environmental and health impacts. Therefore, a more integrated policy approach is needed, as well as better communication to increase public understanding and support for this innovation.

Keyword: Dengue Fever, Gene Drive, Wolbachia, Policy, Field Trial, Vector Control.

INTRODUCTION

Indonesia is a tropical country with two seasons, the dry and rainy seasons. When the dry season begins, mosquitoes are very abundant, while during the rainy season, mosquito eggs tend to breed more because there is more stagnant water available. This triggers the growth and proliferation of mosquito larvae. Transmission of the dengue virus to humans through the intermediary of a mosquito bite known as Aedes Aegypti causes dengue hemorrhagic fever (DHF) (Akbar & Syaputra, 2019). DHF becomes severe when blood vessels are damaged and leaky, causing the number of clot-forming cells (platelets) in the bloodstream to drop (Halodoc, 2024). Signs of dengue fever include sudden fever for approximately 2-7 days with no known cause accompanied by weakness, fatigue, lethargy, heartburn, restlessness, and red spots on the

skin, and bruising (ecchymosis) or rash (purpura) (Tarigan & Yuliani, 2020). Dengue fever is a frightening specter for humans because it can take lives in a relatively short period of time. Dengue fever has increased 30-fold over the past 50 years. The World Health Organization (WHO) estimates that 50-100 million people in the world are affected by dengue every year. The spread of dengue fever first occurred in 1950 in the Philippines and Thailand (Irfandi, 2018). In Indonesia, dengue fever was first discovered in Surabaya City in 1968, where 58 people were affected and 24 of them died. Then the disease began to spread to various regions in Indonesia until finally in 1980 all provinces in Indonesia were infected with DHF (Yuningsih, 2018).

Indonesia is a country that upholds human rights so as to give birth to the right to obtain health as a human right and refers to Article 25 of the Universal Declaration of Human Rights (UDHR) which essentially states that everyone has the right to an adequate life for health services and the welfare of himself and his family. Health in the 1945 Constitution is one of the state's duties, namely to improve public welfare, so it must be realized in various health efforts in a comprehensive and integrated manner and supported by a national health system. Then Law Number 17 of 2023 concerning Health Article 4 states that everyone has the right to health. The state has a mandate contained in Article 34 paragraph (3) of the 1945 Constitution, namely that the state is responsible for the provision of proper health care facilities and public service facilities. So the state has the right to find solutions to reduce the number of infections and deaths from dengue fever.

Scientists started using gene drive techniques around the 1940s with the aim of eliminating disease vectors from the environment. Gene drive techniques are built on the idea of selfish genes or naturally occurring selfish genetic DNA, such as chromosomes, genes, or non-coding DNA (Hillary & Caesar, 2021). CRISPR-based gene drives are selfish genetic elements that are useful for sustainable mosquito vector control and must be able to compete with wild populations of Anopheles gambiae in Sub-Saharan Africa. The gene driver is designed to target within the female-specific doublesex gene isoform, which encodes a key sex-determining regulator in insects. Females homozygous for the gene driver exhibit a female-male sexual development (intersex) unable to produce offspring based on age reared in an environment that induces some of the mosquito behaviors observed in the environment (Hammond, Pollegioni, Persampieri, North, Minuz, Trusso, Bucci, Kyrou, Morianou, Simoni, Nolan, & Müller, 2021). On this occasion, the Government launched a program that seeks to stop the ability of these mosquitoes to transmit the dengue virus. The method uses a natural bacteria called Wolbachia, which lives in insect cells and is passed from one generation to the next through insect eggs. Wolbachia is naturally found in 60% of insects, including fruit flies, moths, dragonflies, and butterflies. The key to success is that if a male insect with Wolbachia mates with a female without Wolbachia, the eggs will not hatch. If the female contains Wolbachia while the male does not, the insect eggs will hatch and all will contain Wolbachia.

If both mosquitoes contain Wolbachia, the eggs will hatch and all will contain Wolbachia. Over several generations, the number of Wolbachia-containing insects will increase dramatically so that at some point most of the insect population will already have Wolbachia. The Wolbachia gene drive from fruit flies is taken using a very small syringe and inserted into the eggs of aedes aegypti and must be done thousands of times until it is finally successful. They then infected the Wolbachia-containing mosquitoes with dengue virus and found something interesting in the dengue virus that could not develop in the mosquito. If the virus cannot develop then it cannot be transmitted to humans. The use of this method was first conducted in Yogyakarta by implementing Wolbachia-infected mosquitoes in 2016 and the number of dengue cases in the city gradually decreased in 2023 to the lowest at 67 cases (Universitas Gajah Mada, 2024).

According to Bagir Manan, policy regulations are regulations that are not directly legally binding even though they still have legal relevance but are only binding for state administrative

bodies or officials themselves (Nalle, 2013). This means that policy regulations are not directly bound but must obey them and can file legal remedies if they feel aggrieved by the policy regulations (Rasji, 2019). In Indonesia itself, the government issued a policy regulation that is specific to the problem of dengue (Directorate General of Disease Prevention and Control, Ministry of Health of the Republic of Indonesia, 2023), following the national strategy related to dengue prevention through strengthening effective, safe, and sustainable vector management, improving access and quality of dengue management, strengthening comprehensive dengue surveillance and responsive outbreak management, increasing sustainable community involvement, strengthening government commitment, program management policies, and partnerships, developing studies, inventions, innovations, and research as the basis for evidence-based policies and program management (Fajarihza, 2023). With policy regulations made by the government, it can help prevent and overcome disease problems in Indonesia. Policy regulations function as an effective instrument of government in providing public services (Rasji, 2023). When viewed from the legal side, it should be able to help solve existing problems, without a supporting and strong legal basis we will be like a ship that loses its way in the middle of the sea and is hit by a storm without knowing how to save itself to the shore (Fauzi, 2020). However, the Wolbachia method itself has drawn various pros and cons from the community (Fajarihza, 2023). Appearing as a contra party include the former Minister of Health: Dr. dr. Siti Fadilah Supari, Scientist: (Dr. Ir. R. Kun Wardama A. MT) (Siti Fadilah Supari Channel, 2023), Komjen. Dharma Pongrekun (Poskota, 2023), Mardigu Wowiek Prasantyo (Bossman Sontoloyo) (Zona Faktual News, 2023), and the community group Majelis Penderitaan Rakyat (Yusuf, 2023). There was also a petition supported by 1,650 people in Denpasar City, Bali due to concerns that the Wolbachia mosquito would cause other diseases, impact the ecosystem and trigger a pandemic (BBC News Indonesia, 2023). On the other hand, there are also those who agree with the spread of Wolbachia mosquitoes. Therefore, if there is an adequate policy regulation, it is possible that it can help solve the problem.

METHOD

This research uses a non-doctrinal method to find correct answers by using proof of the truth sought or from social facts that have legal meaning as heard in everyday life or facts that have been interpreted and become part of the world, meaning in the environment of a particular society (Wignjosoebroto, 2013). This is indicated by the use of primary data collected in the field as a priority, which is preceded by a literature study by examining primary and secondary legal materials to improve the quality of interpretation. The typology of this legal research is explanatory, namely research that explains more deeply about an object of research issues. The explanatory nature of this research is shown through the utilization of previous similar studies as references. The results of this research are intended to complement the findings of previous similar studies.

Primary data collected through field studies were conducted using interview instruments. Data collection through interviews was conducted with several competent resource persons. Secondary data collected in this research is through literature studies conducted through offline and online. All data (primary and secondary) collected were then obtained and analyzed qualitatively with deductive logic by placing primary legal materials and secondary legal materials as major premises and interview results as minor premises.

RESULTS AND DISCUSSION

Implementation of policy on dengue fever treatment through Wolbachia bacteria Gene Drive

The implementation of the policy on the trial of dengue fever management through the Gene Drive of Wolbachia bacteria is being carried out in several regions in Indonesia. Wolbachia is

a bacterium that can infect insects such as the Aedes aegypti mosquito, which is the vector of dengue fever. Wolbachia can inhibit the development of dengue virus in mosquitoes so that Wolbachia-infected mosquitoes cannot transmit dengue virus to humans the situation of a person who is required to be legally responsible for a legal act is aimed at the direct perpetrator, namely a person who directly carries out the act in question. In relation to land registration, the subject of the legal responsibility is the National Land Agency through the General Official, namely the Land Deed Making Officer.

Gene drive technology was used to accelerate the spread of Wolbachia in the Aedes aegypti mosquito population. In this trial, Wolbachia-infected mosquitoes are released into the environment and will breed with wild mosquitoes. The resulting offspring will carry Wolbachia and will gradually replace the wild mosquito population that is not infected with Wolbachia. Trials in various regions in Indonesia, such as Yogyakarta, Sleman, Bantul, Semarang, and Denpasar, have demonstrated the effectiveness and safety of Wolbachia in reducing dengue fever cases and received high support from the community The trial results showed that the spread of Wolbachia through Gene Drive technology could reduce the number of Aedes aegypti mosquitoes by 80% and reduce dengue fever cases by 77%. However, this trial is still in its early stages and further research is needed to evaluate the effectiveness and safety of this technology in the long term (Kemenkes RI, 2023). Benefits and positive impacts:

a. Reduction of dengue fever cases: Trials in various parts of Indonesia have shown a 77% reduction in dengue cases and an 86% reduction in hospital admissions.

b. Community acceptance: Community enthusiasm for the implementation of the Wolbachia method was high, with approximately 95.63% supporting the implementation of the Wolbachia method in their neighborhoods (Kemenkes RI, 2023).

Risks and negative impacts: a. Long-term impacts: Although initial trials have shown its effectiveness, a risk analysis is needed to understand the long-term impacts of Wolbachia on humans, animals and the environment (MOH RI, 2023); b. Safety: Despite claims that Wolbachia is safe for the environment, animals and humans, there is a need for continuous monitoring and evaluation of its safety and impact. c. Community concerns: Some people still have concerns regarding the impact of Wolbachia technology, so good socialization is needed to address the community's doubts.

Thus, the implementation of Wolbachia technology through gene drive method offers the potential to reduce dengue fever cases, but needs to be continuously monitored and evaluated to understand its long-term impact and ensure safety for the environment and humans.

To implement the policy of piloting dengue fever treatment through gene drive of Wolbachia bacteria, several steps must be taken, among others:

a. Research and Risk Analysis: Prior to implementation, research and risk analysis should be conducted to understand the effectiveness and long-term impacts of Wolbachia on humans, animals, and the environment (BBC News Indonesia, 2023);

b. Socialization and Education: Socialization and education to the community needs to be conducted to introduce Wolbachia technology and provide an understanding of the benefits and risks of implementing this technology.

c. Cooperation and Coordination: Cooperation and coordination between the government, health institutions, and communities need to be enhanced to ensure the successful implementation of Wolbachia technology.

d. Monitoring and Evaluation: Monitoring and evaluation of the implementation of Wolbachia technology needs to be conducted continuously to ensure its safety and effectiveness in managing dengue fever.

By taking these steps, it is expected that the implementation of the policy on dengue fever treatment through gene drive of Wolbachia bacteria can be carried out effectively and safely.

a. Selection of This Population: Select Aedes aegypti populations to be infected with Wolbachia. This population should come from an area with dengue transmission.
b. Wolbachia infection: Infection of Wolbachia bacteria into the Aedes aegypti population. This is usually done in a non-harmful manner, such as using infected larvae or by controlled genetic transfer techniques.
c. Observation and Monitoring: After infection, Wolbachia bacteria will infect Aedes aegypti cells and reduce their ability to spread the dengue virus. During the trial period, observation and monitoring will be conducted to observe the level of virus transmission in the infected Aedes aegypti population. d. Data Analysis: Data collected during the trial were analyzed to determine the effectiveness of Wolbachia treatment in reducing dengue transmission.
d. Policy Determination: Based on the results of the analysis, policies for implementation of population control of Wolbachia-infected Aedes aegypti are developed. This may include controlling the use of infected larvae, environmental control, or other techniques to reduce the population of Aedes aegypti.
e. Evaluation and Adjustment: Once the policy is implemented, an evaluation is conducted to determine its effectiveness in reducing dengue virus transmission. Based on the results of the evaluation, adjustments to the policy may be necessary.
It is important to note that the implementation of this policy should be done in consideration of relevant ethical and legislative aspects. In addition, testing and evaluation should be conducted on an ongoing basis to ensure that these solutions are effective and safe for the environment and society. In his inaugural speech, Rasji revealed that policy regulations have been formed and used by all levels of government officials, even by state institutions/officials, their emergence is uncontrolled and many are detrimental to the legal rights of the community, there are no regulations governing them, and there are no officials/institutions authorized to test them (Rasji, 2023).
It is known that the policy regulations on the Wolbachia program mandated in the Decree of the Minister of Health Number HK.01.07/Menkes/1341/2022 on the Implementation of the Wolbachia Method Countermeasure Pilot Project, following Letter Number PM.01.11/MENKES/591/2016 dated 8 November 2016, regulates the management of the 3M Plus PSN Mosquito Nest Eradication with the Movement of one house in one Jantik Jentik (Jumantik). Other programs such as the use of abate are accommodated by the Minister of Environmental Health's Regulation on the Implementation of Environmental Health Services at Puskesmas.

Factors s Affecting the Implementation of the Wolbachia Mosquito Trial Policy
Government and Local Authority Support: The level of support and commitment from local governments and health institutions is critical to successful implementation. This includes adequate budget allocation, necessary licenses, and supportive regulations. Support from local government and health authorities is critical in implementing the Wolbachia mosquito trial policy. This includes several aspects (Caragata & O'Neill, 2016):
a. Budget Allocation: The government needs to provide sufficient budget to support all stages of the pilot, from preparation to implementation and monitoring. An adequate budget allows for the availability of resources such as personnel, equipment and necessary infrastructure.
b. Licensing and Regulation: Local authorities should provide the necessary licenses for the trial activities, including permission to release Wolbachia mosquitoes into the environment. Clear and supportive regulations are also needed to ensure the activities comply with safety and environmental standards.

c. Commitment and Support: Active support from government leaders and local health authorities is essential to ensure program success. This commitment is reflected in participation in meetings, extension campaigns, and direct support to the implementation team.
d. Inter-Agency Coordination: Good cooperation between various government agencies, such as health, environment, and urban planning departments, is needed to harmonize various activities related to the Wolbachia mosquito trial.

In Puskesmas Pandak II Bantul Regency, Mr. Joko Wuryanto as the sanitarian in charge of monitoring the implementation of the Wolbachia program and distributing transportation money to cadres said that in the implementation of this program, the Puskesmas was only in contact with the Faculty of Medicine, Gajah Mada University. He did not understand that the Wolbachia program was a government program. This is understandable because in Bantul Sub-district, especially Panda II Community Health Center, the Wolbachia program has been implemented since 2018, while the policy regulation from the Ministry of Health has only been implemented since 2022, namely with the stipulation of the Minister of Health Decree Number HK.01.07/Menkes/1341/2022 on the implementation of the Wolbachia Method Dengue Prevention Pilot Project, which was then followed up with the Decree of the Director General of Disease Prevention and Control on Technical Guidelines for the implementation of Wolbachia Method Dengue Prevention (Interview, 2024).

With strong support from the government and local authorities, the implementation of the Wolbachia mosquito trial policy can run smoothly and effectively, increasing the chances of success in controlling disease-carrying mosquito populations.

Resource Availability: The availability of funds, personnel, and infrastructure are critical factors in the implementation of a pilot. Without adequate support, implementation may be hampered. Resource availability is a key factor in the successful implementation of the Wolbachia mosquito trial policy. This includes several aspects:

1. Funds : Implementation of the Wolbachia mosquito trial policy requires significant financial investment. Funds are required for various activities, including research, production of Wolbachia mosquitoes, monitoring, evaluation, and community outreach campaigns.
2. Personnel: The implementation team needs trained and qualified personnel to carry out various aspects of the trial activities, including field monitoring, data analysis, communication with communities, and project administration.
3. Infrastructure: Adequate infrastructure is required to support various stages of the activities, ranging from laboratories for Wolbachia mosquito production to field monitoring facilities and transportation.
4. Equipment and Materials: Laboratory equipment, mosquito monitoring devices, chemicals, and other field equipment are required to support testing and monitoring activities.

Dr. Susilo Pradyanto as the Head of Sandrakh Health Center of Wates District said that in Wates Sub-district the Wolbachia program has not been implemented but other programs from the Government such as the distribution of abate and fogging are running well by involving inter-agencies such as the Civil Service Police unit (Satpol PP), Sub-district, Police, Police and the Puskesmas itself. He said that the decrease in dengue cases in Watas is quite significant by improving the way of fogging. Initially, fogging was carried out in rotation from location to location, now the development of fogging methods is carried out simultaneously in several locations at the same time (Interview, 2024). The availability of adequate resources will ensure that all stages of the trial run smoothly and efficiently, and increase the chances of success in controlling disease-carrying mosquito populations.

Community Participation: Active engagement and participation of local communities is important to support and facilitate activities such as monitoring, education and surveillance. Active participation of local communities is essential in the implementation of the Wolbachia mosquito trial policy. Some aspects to consider in this regard are (Interview, 2024):

1. Knowledge and Understanding: It is important to provide clear and accurate information to the community on what Wolbachia mosquitoes are, the purpose of the trial, and its benefits in controlling mosquito-borne infectious diseases. The better the community's understanding of the program, the more likely they will support it.
2. Involvement in Educational Activities: Conducting outreach and education activities on Wolbachia mosquitoes to local communities can help increase their awareness and understanding. This can be done through seminars, workshops, group meetings, or other communication media.
3. Participation in Monitoring: Involving the community in Wolbachia mosquito monitoring activities can help in collecting wider and more accurate field data. Communities can help report the presence of mosquitoes and environmental conditions that affect mosquito populations.
4. Involvement in Monitoring and Reporting: Communities can also play a role in monitoring trial implementation activities, providing feedback, and reporting issues or events of concern to the appropriate authorities.
5. Support in Policy Implementation: Communities that support the Wolbachia mosquito trial policy can help facilitate the implementation process by providing access to their areas, allowing the installation of monitoring devices, or even participating in community campaigns.

From interviews conducted with the community around SDN 03 Sungapan, Galur Sub-district, Kulon Progo Regency, it was found that respondents did not understand the Wolbachia program and there were even respondents who had heard of the Wolbachia program but did not agree to the implementation of the program. Some of the reasons given were the increase in mosquito population and the fear of the adverse effects of mosquito bites due to the program (Interview, 2024).

With strong participation from the local community, the implementation of the Wolbachia mosquito trial policy can be more effective and sustainable, as the community will feel ownership of the program and actively contribute to disease control efforts.

Technical Readiness: Successful implementation also depends on the technical readiness of the implementation team, including the ability to collect data, laboratory analysis, and field monitoring. Technical readiness is the ability of the implementing team to manage and execute all technical aspects associated with the implementation of the Wolbachia mosquito trial policy. This includes several aspects:

1. Data Collection: The implementation team should be able to collect relevant data related to mosquito populations, the spread of mosquito-borne diseases, and the impact of the pilot policy. This data is important to guide decision-making and evaluate the effectiveness of the program.
2. Laboratory Analysis: Skills in conducting laboratory analysis are required to examine mosquito samples, identify the presence of Wolbachia bacteria, and evaluate the level of infection.
3. Field Monitoring: The implementation team should be able to effectively conduct field monitoring to observe mosquito populations, assess the impact of Wolbachia release, and identify changes in disease spread.
4. Project Management: Good project management skills are required to coordinate various activities within the stipulated time and within the available budget limits.
5. Communication: The ability to communicate with various stakeholders, including local communities, local governments, and health institutions, is critical to ensure a good understanding of the program and support community participation

The results of the interview with Mr. Joko Wuryanto as the sanitarian of Puskesmas Pandak II said that although the implementation of the Wolbachia program has been carried out, he has not received data on the evaluation results of this program other than information on the

reduction of dengue fever cases (Interview, 2024). Good technical readiness will ensure that all operational aspects of the Wolbachia mosquito trial policy can be implemented properly, thereby increasing the likelihood of the program's success in controlling disease-carrying mosquito populations.

Community Compliance and Acceptance: The level of community awareness, understanding and acceptance of the program may affect the success and sustainability of the trial. Community understanding and acceptance of the Wolbachia mosquito trial policy is critical for successful implementation. Explaining and educating the community on the objectives, benefits and implementation process of the policy will help to create a better understanding. The following are some relevant points (Nazni, Hoffmann, NoorAfizah, Cheong, Mancini, Golding, & Sinkins, 2019):

1. Awareness of health issues: Communities need to be aware of the dangers posed by disease-carrying mosquitoes and the importance of mosquito population control efforts to prevent the spread of disease.
2. Understanding of Wolbachia: The public needs to be informed about Wolbachia bacteria and how its use can help control mosquito populations. A clear and accurate explanation can help dispel any concerns or confusion that may arise.
3. Participation in the program: Community acceptance of the policy will increase their participation in the program, such as providing access to sites for Wolbachia mosquito release or reporting mosquito-related events.
4. Trust in health authorities: The success of the program also depends on the level of trust the community has in the health authorities and the policies they implement. Transparency, openness, and effective communication from the authorities will help build this trust.
5. Awareness of environmental and health impacts: Communities need to be made aware of the environmental and health impacts of this policy, including the potential risks and long-term benefits.

The government should socialize the results of the Wolbachia program in the community that there were people who contracted dengue fever but the patients did not spread dengue fever even to other family members and neighbors because the aedes aegypti mosquito as the carrier of the dengue fever virus was not present in the location.

By having a good understanding and acceptance of the Wolbachia mosquito trial policy, the community will be more likely to support and actively participate in the program, which in turn will increase the chances of success in controlling disease-carrying mosquito populations.

CONCLUSION

Implementation of the policy on the trial of dengue fever management through gene drive of Wolbachia bacteria has not been accompanied by risk analysis and has not considered ethical and legislative aspects, testing and evaluation have not been conducted in groups.

The implementation of the Wolbachia mosquito trial policy was influenced by Government and local authority support, resource availability, and community participation, technical readiness, as well as community compliance and vetting.

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