

## PUBLIC HEALTH POLICY FORMULATION STRATEGY IN ANTICIPATION OF MEDICAL TECHNOLOGY DEVELOPMENTS AND REGULATORY CHALLENGES IN THE ERA OF HEALTHCARE DIGITALIZATION

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### Abstract

This study aims to analyze the strategy of public health policy formulation in the face of medical technology developments and regulatory challenges that arise in the era of digitalization of health services. The method used is normative with a literature study approach from relevant books and journals to understand the legal foundations, technological implications, and aspects of digital regulation regulation in the health sector. The results of the study show that policy formulation needs to integrate aspects of the adaptation of the latest medical technologies while strengthening a regulatory framework that is responsive to rapid changes in the field of digitalization of health services. A collaborative approach between the government, health workers, and technology players is key in developing effective and sustainable norms. Policies must be able to ensure the security of patient data, digital medical practice standards, and access and equitable distribution of technology-based health services. Regulatory challenges arise due to the rapid pace of technological innovation that has not always been balanced by adequate legal provisions, so it is necessary to have a mechanism for periodic evaluation and revision of policies to maintain a balance between innovation and public protection.

**Keywords:** *policy formulation, medical technology, digitization of health services.*

### INTRODUCTION

The rapid development of medical technology has brought significant changes to the healthcare sector around the world. Digital transformation is not only affecting the way diagnosis and treatment are carried out, but also changing the pattern of interaction between medical personnel and patients who are increasingly dependent on information technology. Innovations such as telemedicine, electronic medical records, digital health applications, and sensor-based patient monitoring systems allow for faster, more extensive, and more efficient access to services. The application of this technology also opens up opportunities for improving service quality, accelerating clinical decision-making, and managing patient data more systematically. On the other hand, the emergence of digital technology brings new challenges related to the aspects of regulation, ethics, and legal protection in the health sector, which require serious attention from all stakeholders (Tunny et al., 2025).

The rapid development of information technology requires an adaptive public health policy that is able to accommodate changes without neglecting aspects of patient safety and

rights. The use of digital data in medical services presents the risk of leakage and misuse of sensitive information, while the lack of clear standards in the implementation of digital medical practices creates legal uncertainty and potential complex ethical issues. This regulatory gap must be addressed immediately so that technological innovations do not threaten the quality of service and patient protection. Strong and flexible regulations will allow new technologies to be applied optimally and safely, supporting the creation of an efficient, safe, and equitable healthcare system (Ulva et al., 20245).

Regulatory challenges arise due to the gap between the pace of technological innovation and the public policy formulation process which tends to be slower. Many of the regulations that exist today are unable to anticipate the various technical, legal, and ethical aspects of digital health technology that continue to evolve. The absence of a periodic evaluation and revision mechanism for regulations can cause policies to become obsolete or irrelevant, causing legal uncertainty for various parties, including the government, health service providers, and digital medical technology users. Non-adaptive policies risk stifling innovation and creating doubts for stakeholders in adopting new technologies, while lowering the quality of patient protection (Yunus & Syukur, 2025).

Cross-sectoral cooperation is the key in formulating health policies that are able to answer these various problems. Governments, health workers, academics, and technology industry players need to be actively involved in intensive dialogue to build adaptive and responsive regulations. A collaborative approach allows for the exchange of information, risk identification, and an in-depth understanding of medical needs and relevant technological aspects. Regulations born from the participatory process also have the potential to have stronger social legitimacy and are widely accepted by the community. In addition, policy formulation must consider equitable access to digital services so that the gap in health services between regions can be minimized and health services can be enjoyed equally by all levels of society.

This research aims to analyze public health policy formulation strategies that anticipate medical technology developments and regulatory challenges in the era of healthcare digitalization. The output of this research is expected to be able to provide policy recommendations that integrate the latest technological adaptation aspects with the strengthening of a responsive regulatory framework. The main focus of this research is how to design sustainable policy evaluation mechanisms and effective collaboration models in order to secure patient data, set digital medical practice standards, and ensure access and equitable distribution of technology-based health services. The need for this research arises from the fact that without proper policy design, digitalization innovations in healthcare have the potential to pose risks that endanger patient safety and healthcare equity.

## LITERATURE REVIEW

### Strategy

Strategy is a plan or pattern of action designed to achieve certain goals systematically and effectively. Strategy involves making the right decisions, optimal allocation of resources, prioritizing, and setting measures to meet challenges and take advantage of opportunities. Strategy demands analysis of the organization's internal and external situation, risk

identification, and adaptive design of solutions to achieve goals efficiently. Strategy implementation also requires continuous evaluation, adaptation to environmental changes, and innovation to maintain sustainability and competitive advantage (Ilyas et al., 2023).

### **Medical Technology Developments**

Medical Technology Developments refers to the process of continuous innovation and advancement in the field of medical technology, encompassing the design, development, and implementation of various medical tools, systems, and procedures. These technologies are applied for the purposes of diagnosing, treating, preventing, and monitoring patients' health, aiming to enhance the overall quality and reliability of healthcare services. The development of new medical technologies allows healthcare providers to deliver interventions with greater precision and efficiency, reducing errors and improving patient outcomes (Solihin & Abdullah, 2023).

Advances in medical technology have led to the integration of medical sciences, informatics, and engineering, creating solutions that are faster, more accurate, and more accessible. Innovations such as surgical robots, digital imaging systems, AI-powered health applications, and portable monitoring devices enable real-time tracking of patients' conditions and facilitate more personalized care. These technological improvements not only enhance the effectiveness and safety of medical treatments but also expand the availability of affordable healthcare services to wider segments of the population (Richard & Ching-Ching, 2021).

### **The Era of Digitalization**

The Digitalization Era marks a period of transformation marked by the widespread use of digital technology for data processing, communication, and increased operational efficiency in various sectors of life. The Internet, smart devices, digital applications, data-driven systems, and process automation are becoming integral parts of this era, enabling real-time access to information and services. Digitalization not only changes the way people work and interact, but also affects resource management patterns, production processes, and public service systems. This change opens up new opportunities for innovation, development of digital business models, and cross-sector collaboration that was previously difficult to reach. Adaptation of regulations, policies, and community skills development is a must so that technology can be used optimally and safely, as well as encourage the creation of an inclusive and sustainable digital ecosystem (Asriwati, 2023).

Digital transformation is also driving new trends in decision-making, data use, and technology-based innovation. Organizations and individuals are required to be able to manage information efficiently, utilize data analytics, and adapt to rapid system changes. Automation enables activities that previously required human resources to be faster and more accurate, but also presents challenges related to data security, privacy, and technology access gaps between regions. The role of digital literacy and the development of technological capabilities is key so that people can take full advantage of the potential of the digital era. Governments, the private sector, and communities must work together to create responsive regulations and an environment that supports innovation while protecting the public interest (Saimi, 2025).

### **Healthcare**

Healthcare encompasses all systems, services, and practices that aim to maintain, improve, and restore human health. Health service activities include promotive, preventive,

curative, and rehabilitative efforts, ranging from basic services at health centers to complex handling at specialist hospitals. This service also involves human resource management, the use of medical technology, health policies, the provision of medicines, and supporting facilities that aim to improve the quality of life of the community. The main focus of health services is to provide effective interventions for individuals and populations, taking into account biological, social, environmental, and behavioral factors, so that people's well-being can be achieved optimally (Cookson et al., 2020).

Healthcare development is not only concerned with the provision of medical facilities, but also involves innovations in procedures, technology, and management systems that improve the quality, efficiency, and accessibility of services. The implementation of digital technologies, such as electronic medical records, telemedicine, and data-driven health applications, enables more accurate patient monitoring, more precise clinical decision-making, and faster and more equitable services. Improving the competence of health workers, strengthening regulations, and developing adaptive policies are the determining factors so that the health system can run effectively, safely, and fairly for all levels of society. Modern health services also require collaboration between various parties, including the government, educational institutions, the health industry, and society, to create an ecosystem that supports the improvement of the quality of life and people's well-being in a sustainable manner (Djuari, 2021).

## **RESEARCH METHOD**

This study uses a normative approach that focuses on literature studies to understand the legal foundations, medical technology developments, and regulatory aspects in digital health services (Kristiawanto, 2022). This approach examines the rules, principles, and norms that apply and how these principles are applied in public policy. The normative focus allows researchers to evaluate the suitability of existing regulations with current technological practices and identify the need for changes or updates in health policies. Literature study is a relevant method because it is able to explore theories, regulations, and the results of previous research to strengthen the analysis and understanding of the issues raised.

The data used in this study was collected through documentation study techniques by utilizing sources in the form of relevant books and scientific journals. The book is used as a reference to obtain a theoretical basis and normative framework related to health law and medical technology regulation. Scientific journals were selected to access the latest information and research results regarding digital health technology and its regulatory challenges. The collection of data through this literature helps to map the development of knowledge and policy in the field being researched in a systematic and comprehensive manner, allowing for the development of arguments based on academic evidence as well as applicable policies.

Data analysis was carried out using content analysis techniques that focused on the interpretation of the text and content of the collected documents. This process involves identifying key themes related to policy formulation strategies, regulatory issues, and the impact of digital technology in the health sector. The researcher examines how these legal and technological concepts interact with each other and assesses the relevance and effectiveness of existing policies. The results of this analysis are then integrated to formulate policy

recommendations in accordance with technological developments and regulatory challenges, in order to produce adaptive and applicable solutions in the context of healthcare digitalization.

## **RESULT AND DISCUSSION**

### **Public Health Policy Formulation Strategy that Accommodates Medical Technology Developments in the Era of Digitalization of Health Services**

The formulation of public health policies that are able to accommodate the development of medical technology in the era of digitalization requires a holistic and adaptive approach. Policies must be able to capture technological changes quickly without sacrificing aspects of security, ethics, and service accessibility. The adaptation of digital medical technology is not only about the application of new tools or systems, but also about how service standards and regulations are developed to align with these innovations. An in-depth understanding of the characteristics of digital medical technology, the potential risks that may arise, and the mechanisms for its integration into the existing healthcare system are the main requirements for policies to be implemented effectively and sustainably. This requires policymakers to not only view technology as a tool, but also as an integral part of complex healthcare management processes (Adinda & Jamal, 2025).

Strengthening a responsive regulatory framework is the main strategy in the formulation of digital technology-based health policies. Regulations must be designed to be flexible in order to adapt to rapid and sometimes unpredictable technological changes. The establishment of a systematic and periodic evaluation mechanism is part of the policy to review existing standards and rules, so that regulations are not stagnant and remain relevant to current conditions. The draft regulation must cover various aspects, ranging from patient data protection, licensing of the use of technology, to standardization of digital-based health services. Thorough rulemaking allows innovation to continue without sacrificing patient safety, while preventing regulatory inconsistencies that can cause obstacles in the application of new technologies (Amallia, 2024).

Collaboration between various stakeholders is the foundation in shaping effective policies. The government, health workers, technology developers, academics, and the public need to be actively involved in the discussion and decision-making process. These interactions allow for better information exchange and a deeper understanding of the benefits and risks of each technological innovation. Multi-stakeholder participation also helps identify problems in more detail and find inclusive solutions. Policies born from the consensus of various parties have a greater chance of gaining strong social legitimacy and being widely accepted by the community, so that their implementation can run more smoothly and effectively (Astuti et al., 2024).

Peningkatan kapasitas sumber daya manusia dalam bidang kesehatan dan teknologi menjadi strategi lanjutan untuk mendukung implementasi kebijakan berbasis teknologi digital. Tenaga kesehatan perlu diberikan pelatihan dan pemahaman mengenai penggunaan teknologi medis digital agar dapat mengoperasikan dan memanfaatkan alat serta sistem secara optimal. Peningkatan literasi digital tidak hanya berlaku bagi tenaga medis, tetapi juga bagi pembuat kebijakan agar lebih adaptif terhadap inovasi teknologi. Edukasi kepada masyarakat sebagai pengguna layanan juga harus diperkuat agar teknologi dapat digunakan secara aman dan

bertanggung jawab. Program pelatihan dan pengembangan kapasitas menjadi fondasi agar penerapan kebijakan dan teknologi dapat berjalan secara efektif dan menghasilkan layanan kesehatan berkualitas (Fauzi et al., 2024).

The principles of justice and equal access are priorities in the adjustment of technology-based health service policies. The development of digital medical technology has the potential to create a service gap between urban and remote areas. Policies need to anticipate this through the provision of incentives, the development of digital infrastructure, and special programs so that digital health services can be enjoyed by all levels of society. Protection of vulnerable groups such as the elderly, people with disabilities, and people with limited access to technology must be ensured so that technology does not become a barrier to the receipt of proper health services. This strategy enables digital healthcare to be not only innovative, but also inclusive and social justice-oriented (Ginting, 2025).

The integration of medical technology into the health system requires a policy framework that balances legal, technical, and ethical aspects. The formulation strategy must prioritize patient data security, technology quality control, and legal protection for users and service providers. Policies must also provide space for innovation without sacrificing the aspect of public protection. With an integrated approach oriented to technological developments and community needs, public health policy can be a key driver of healthy, safe, and inclusive digital transformation in the health sector.

### **Regulatory Challenges Due to the Rapid Innovation of Digital Health Technology and Its Handling Mechanism**

The regulatory challenges that arise due to the rapid innovation of digital health technology are very diverse and complex, affecting various aspects in the health sector. One of the main challenges is the protection of patients' personal data. Digital health data is so sensitive that it requires a robust regulatory framework to ensure information security and maintain patient privacy. The leak or misuse of medical data can have serious impacts, including a loss of public trust in the digital health system. Inadequate regulations on data protection result in vulnerability to cyberattacks and privacy breaches, so it is necessary to strengthen security standards (Hasnah & Asyari, 2024).

The technology access gap is another significant challenge in the application of digital health technology. Not all regions or communities have adequate infrastructure such as stable internet and the technological devices needed to take advantage of digital healthcare. This creates inequality that has the potential to widen the gap between urban and rural areas. The government and stakeholders must design mechanisms that can ensure equitable access to health technology so that all levels of society can enjoy the benefits of digitizing health services fairly (Hasyim, 2024).

The availability of adequate technological infrastructure is also still a major obstacle. Many health facilities, especially in remote areas, have not adopted digital information systems to the maximum. This condition causes health data integration to run not optimally because data is still scattered across various platforms that are not connected to each other. This system irregularity causes difficulties in data exchange between health institutions and hinders service efficiency. Regulations need to direct standardization and interoperability between systems so that the health technology ecosystem can be well connected (Hidayatuloh & Utoyo, 2025).

In addition, the challenges of health data governance and interoperability are critical issues. Many institutions use different data standards and formats, making it difficult to consolidate information. This is not only a technical issue, but also a matter of trust between related parties in data sharing that must be clearly regulated so that data is used for legitimate purposes. Regulations governing data governance must be able to create a balance between the need for public health policy analysis and the strict protection of individual privacy rights (Laksono, 2022).

New digital medical practices also pose ethical and legal challenges. Regulations should provide legal certainty regarding medical liability in the use of digital technologies, such as telemedicine and health apps. The absence of clear operational standards of procedures can pose a risk of malpractice and misuse of technology. The policy needs to regulate in detail the rights and obligations of health workers and consumers of digital services so that digital medical practices run according to the rules and are able to protect all parties involved (Lukito & Gani, 2024).

### **The Role of Collaboration of Government, Health Workers, and Technology Actors in Building a Responsive Regulatory Framework**

Collaboration between the government, health workers, and technology players plays a strategic role in building a regulatory framework that is responsive to the development of digital health technology while ensuring patient data security and equitable access to services. The government serves as a regulator that formulates policies and technical regulations that regulate the legal and ethical aspects of the use of digital medical technology. Through programs such as the Ministry of Health's Regulatory Sandbox, the government creates a testing room and assists digital innovation so that technology development can run in line with applicable safety and service quality standards. The government's active involvement ensures that regulations are able to keep up with highly dynamic technological innovations and prevent violations that can endanger patients and health workers (Mamesah et al., 2025).

Health workers contribute to the implementation and adjustment of medical practices that use digital technology, so that the policies formulated are not only theoretical but also applicable in the field. The involvement of medical personnel in the regulatory process helps ensure that service standards are maintained and the risk of medical errors caused by digital technology can be minimized. Health workers also act as supervisors and reporters of policy implementation in field practice and provide input for regulatory improvements to suit the actual and ethical needs of the profession. Equitable access to digital health services also depends on the readiness of health workers to use technology systems to the maximum in various regions (Melliasari et al., 2024).

Technology players as solution providers and developers of digital platforms have a role in presenting innovations that are not only sophisticated but also safe and easily accessible to various groups of people. Technology industry players must comply with the data security standards set, as stipulated in the Personal Data Protection Law Number 27 of 2022 and the Regulation of the Minister of Health Number 24 of 2022 concerning Electronic Medical Records. Collaboration with the government and health workers needs to be carried out intensively so that the technology developed is in accordance with the needs of users and applicable regulations. Through this collaboration, technological innovations can be fostered

and tested in an adaptive regulatory environment, reducing the risk of implementation failure in the field (Rupawan & Fadilah, 2025).

Securing patient data is one of the main aspects that this collaboration focuses on. Regulations such as Law Number 27 of 2022 concerning Personal Data Protection require explicit patient consent, the implementation of double authentication, and data encryption as security standards. The government oversees the implementation of these standards through various mechanisms involving audit and monitoring. Health workers and technology players are required to carry out these security procedures in daily operations so that patient data is not leaked and misused. The implementation of this standard also strengthens public trust in utilizing digital health services (Santoso et al., 2025).

Equitable access to digital health services can be achieved through policies that encourage the development of digital infrastructure in all regions, especially remote areas that have experienced limited access. The government has prepared regulations that support incentives for infrastructure procurement and training of health workers in the regions to accelerate the adoption of technology. The collaboration of technology players with health workers at the regional level helps to adjust digital solutions that suit the local characteristics of the community. A system of continuous monitoring and evaluation is necessary for the distribution of services to run effectively without leaving vulnerable groups or underserved areas (Sitorus, 2024).

Some of the regulations that have been a strong foundation in building a regulatory framework for digital health services in Indonesia include Law Number 17 of 2023 concerning Health which accommodates telemedicine services, Government Regulation Number 28 of 2024 which regulates digital health service infrastructure, and Law Number 27 of 2022 concerning Personal Data Protection which emphasizes the security aspect of patient data. Regulation of the Minister of Health Number 24 of 2022 concerning Electronic Medical Records and Permenkes Number 20 of 2019 concerning the Implementation of Telemedicine Services are technical guidelines for the implementation of digital medical services. In addition, the implementation of the Ministry of Health's Regulatory Sandbox program provides space for technological innovations that are tested and fostered within an adaptive regulatory framework to strengthen a safe, effective, and inclusive digital health service ecosystem.

## CONCLUSION

Public health policy formulation must be able to anticipate the development of medical technology and regulatory challenges that arise due to the era of digitalization of health services. The policies drafted need to integrate the latest medical technology adaptations while strengthening a regulatory framework that is responsive to rapid changes in digital technology. The security of patient data, digital medical practice standards, and equitable access to technology-based services are the main focuses that must be guaranteed. Regulators should create mechanisms for periodic policy evaluation and revision to remain relevant and balanced between innovation and public protection. This research confirms that collaboration between the government, health workers, and technology players greatly determines the success of effective, adaptive, and sustainable policy formulation for the national health system.

Policy strategy recommendations include strengthening regulations that regulate the protection of personal data based on Law Number 27 of 2022 concerning Personal Data Protection, as well as the implementation of technical standards such as the Regulation of the Minister of Health Number 24 of 2022 concerning Electronic Medical Records and the Minister of Health Regulation Number 20 of 2019 concerning Telemedicine Services. The government needs to continue to optimize the Regulatory Sandbox program to support digital technology innovations in accordance with regulations. Increasing the capacity of human resources in the health and technology sectors, developing equitable digital infrastructure, and ensuring inclusive access are the main supporters so that policies can be implemented optimally. Policies must prioritize the principle of fairness so that digital health technology does not widen the service gap between regions and community groups so that safe, effective, and equitable digital health services are created.

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