



THE LEGAL REVIEW OF INTRACEREBRAL ARTERIAL HEPARIN FLUSHING MEDICAL PROCEDURE AS A NON-EVIDENCE BASED THERAPY

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ABSTRACT

The implementation of medical practice must follow service standards. The purpose of this study is to determine the quality of medical services based on scientific evidence. The research method used was normative juridical, the results of the study state that in efforts to improve the quality of medical services in Indonesia, the government had set health service standards as binding laws for health workers. However, these service standards are often not always implemented, so they have the potential to cause deviations that are detrimental to the community. Quality medical services based on scientific evidence are the main paradigm for quality medical services and community protection. Currently, there are still medical actions that are not based on scientific evidence, intracerebral arterial heparin flushing but have been widely applied and commercialized. intracerebral arterial heparin flushing is an action that is not based on strong scientific evidence so it is unethical. Therefore, legal protection is needed for the community from medical actions that are not based on scientific evidence. Medical personnel are advised to comply with service standards and carry out medical practices based on scientific evidence in carrying out their profession in order to avoid violating the law.

A. INTRODUCTION

The state guarantees the fulfillment of public health rights in accordance with the values of justice, expediency, and legal certainty as stated in the 1945 Constitution Article 28 H paragraph (1), which states that Everyone has the right to live in physical and mental prosperity, to have a place to live, to have a good and healthy environment, and to obtain health services. One of the aims in establishing the Republic of Indonesia Unified State asset forth in the Preamble of the Republic of Indonesia's 1945 Constitution is to improve the people's welfare.¹ Health services in the form of basic medical services and/or specialized medical services aim to maintain and improve the health status of the community through standardized preventive, diagnostic, and therapeutic efforts.

With the passing of the Omnibus Law on Health issue on August 8, 2023 and recorded in the official gazette as Law No. 17 of 2023 on Health², Law No. 29 of 2004³ and Law No. 36 of 2009⁴ are automatically included in the new law. Law No. 17 of 2023 states that doctors or dentists in organizing medical practices must follow the standards of medical or dental services.

Medical procedure is a treatment that can be operative or non-operative with the aim of treating, caring for, and restoring the health of patients. Medical procedures that are carried out based on certain routine work will be made a set of instructions or steps that are standardized and universally applicable wherever doctors provide services in accordance with Permenkes Number 1438 of 2010 concerning Medical Service Standards.⁵

These medical service standards apply nationally to demarcate the autonomy of the medical profession and also to protect society as a whole.⁶ However, in practice, there are many differences in the way patients are treated, differences in the availability of facilities or equipment used, so that all of this can cause deviations that harm the public. In order to support the independence and implementation of the medical profession in health services, the government stipulates the enactment of medical service standards in hospitals and hospital service standards. The medical service standards are a major milestone in efforts to improve the quality of medical services in Indonesia.

This medical service standard is a law that binds parties who work in the health sector, namely to regulate health services and prevent negligence of medical staff in performing medical procedures.⁷ In relation to the

1 Arief Budiono (etc.), Black Swan Theory: Legal Policy of the Indonesian National Healthcare, *Legality: Jurnal Ilmiah Hukum* 30, No. 1 (March-2022): 29-46

2 Law No. 17 of 2023 on Health

3 Law No. 29 of 2004 on Medical Practice

4 Law No. 36 of 2009 on Health

5 Minister of Health Regulation No. 1438 of 2010 Concerning Health Service Standards

6 Frederic W. Hafferty and Donald W., Light, Professional Dynamics and the Changing Nature of Medical Work, *Journal of Health and Social Behavior*, (1995): 132-153

7 Nadya Adianie and Gunawan Djajaputra., Illegal and Unauthorized Medical Treatment in Therapeutic Transactions, *UNES Law Review* 6, No. 4 (2024): 9947-9956

medical profession, medical service standards are needed which include staffing standards, procedure standards, and facility standards, as well as expected outcome standards. In addition, medical service standards are not only to measure the quality of service but also to serve the interests of the evidentiary process in court.

Over the past quarter century evidence-based medicine (EBM) has emerged as a major paradigm in the diagnosis and treatment of disease. According to Sackett, Evidence-based medicine (EBM) is a medical approach based on the latest scientific evidence for the benefit of patient health services. In practice, EBM combines clinical skills and experience with the most reliable current scientific evidence.⁸

The hallmark of an evidence-based medical service or procedure is that it uses diagnostic and therapeutic modalities formulated based on EBM principles that are published in the literature, guidelines, protocols, indexed journals, and can be peer-reviewed.⁹ Whereas medical services or medical procedures that are not evidence-based, are generally medical procedures that are not common and are not guided by the scientific principles of modern medicine whose decision-making is still based on old or conventional methods, namely based on mere testimonials. This non-evidence-based medical service is not only likely to not provide benefits to patients, can cause significant harm, and facilitate fraud and sham practices carried out by registered and unregistered health practitioners.¹⁰

There is a new hope for better medical care through the legal realm. Practitioners who provide clinical services based solely on faith, intuition and experience are increasingly marginalized and subject to disciplinary action for engaging in the provision of services that do not have a proper medical scientific basis.¹¹ For this reason, one of the main requirements to facilitate evidence-based clinical decision-making is to provide scientific evidence that is relevant to the clinical problem at hand. The preferred scientific evidence is the results of meta-analyses, systematic reviews, and the results of randomized controlled trials. A doctor who performs medical actions or procedures that are not in accordance with professional standards, National Guidelines for Medical Practice (PNPK), medical service standards, and Standard Operating Procedures (SOP) may face legal problems. Conducting evidence-based medical action (EBM) will increase protection and dignified justice and better medical services for patients.¹²

8 DI Sackett (etc.), *Evidence-Based Medicine. Evidence Based Medicine-How to Practice and Teach EBM. 2nd Edition*, (London: Churchill Livingstone, 2000): 5-7.

9 Swanson, J. A., Schmitz, D., & Chung, K. C., How to practice evidence-based medicine. *Plastic and Reconstructive Surgery* 126, No. 1 (2010): 286-294.

10 Freckelton Sc., I. *Evidence-based medicine and the law. Legal and Forensic Medicine*. 2013, page 109-118

11 Bas de Boer and Olya Kudina., What Is Morally at Stake When Using Algorithms to Make Medical Diagnoses? Expanding The Discussion Beyond Risks and Harms, *Theor Med Bioeth* 42, (2021): 245-266

12 Muas Mubarak., Didit Darmawan and Rio Saputra, Legal and Ethical Arrangements for Medical Record Filling by Doctors: A Normative Study, *Bulletin of Science, Technology and Society* 2, No. 1 (2023): 33-38

Previous research stated that there were no references supporting that IAHF could improve motor (muscle) function in chronic ischemic stroke patients.¹³ Further research conducted by Arief Kurniawan stated that there were systemic errors in the IAHF Study Team's research. Bias causes weaknesses in the aspects of objectives, methodology, results, conclusions and research suggestions. To increase the level of evidence and class of IAHF action recommendations, it is necessary to conduct Randomized Controlled Trial research in several hospitals with strict supervision of the research protocol.¹⁴ Further research conducted by Terawan Agus Putranto stated that IAHF treatment can significantly improve CBF value in chronic ischemic stroke patients. This study gives a new hope that reperfusion therapy with IAHF can give benefit to increase microcirculatory function to support penumbral recovery with a wider window therapy.¹⁵

Currently, there are various health services performed by medical practitioners that are not evidence-based. One example of a medical procedure that is not evidence-based and has been widely applied to the general public, among others, is the medical procedure of Cerebral Intra-Arterial Heparin Flushing (IAHF) as a therapy for male impotence, autism, etc. which is unethical and not based on scientific evidence. Therefore, there is a need for legal protection for patients from medical procedures that are not evidence-based.

This study aims to examine the challenges of evidence-based medicine in the implementation of IAHF procedures; reviewing the quality of medical services based on scientific evidence; analyze legal aspects of medical procedures that are not based on evidence; as well as analyzing the relevance of IAHF as an aspect of legal therapy for medical procedures based on evidence.

B. RESEARCH METHODS

Research method used normative juridical, the conceptual approach offers nuanced philosophical explanations to understand why the law, including the legal discourse itself, appears and applies in societies.¹⁶ The approach in this research used a Conceptual Approach and an Analytical Approach.¹⁷

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- 13 Moh Hasan Machfoed (etc),. Does Intra-Arterial Heparin Flushing (IAHF) Can Actually Increase Manual Muscle Test (MMT) Score in Chronic Ischemic Stroke Patients? *Folia Medica Indonesiana* 52, No. 2 (2016): 148-153
 - 14 Arief Kurniawan and Nur Pudyastuti Pratiwi., Kontroversi Terapi Dsa Pada Gangguan Vaskuler Otak, *Journal of Innovation Research and Knowledge* 1, No.11 (April 2022): 1491-1496
 - 15 Terawan Agus Putranto (etc),. Intra Arterial Heparin Flushing Increases Cerebral Blood Flow in Chronic Ischemic Stroke Patients, *The Indonesian Biomedical Journal* 8, No.2 (August 2016): 119-26
 - 16 Tunggul Ansari Setia Negara., Normative Legal Research in Indonesia: Its Origins and Approaches, *ACLJ: Audito Comparative Law Journal* 4, Issue. 1 (2023): 1-9
 - 17 Moh. Mujibur Rohman (etc),. Methodological Reasoning Finds Law Using Normative Studies (Theory, Approach, and Analysis of Legal Materials), *MAQASIDI: Jurnal Syariah dan Hukum* 4, No. 2 (December 2024): 204-221

C. RESULTS AND DISCUSSION

1. The Challenges of Evidence-Based Medicine in Implementing IAHF Procedures

Health is a human right and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian nation as referred to in Pancasila and the 1945 Constitution of the Republic of Indonesia.¹⁸ Since 2012 until now, an interventional medical procedure called Cerebral Intra-Arterial Heparin Flushing (IAHF) or introduced as "brainwash" has been performed in Indonesia, which is a modification of Digital Subtraction Angiography. Digital Subtraction Angiography is an accurate imaging technique to evaluate the presence of vascular abnormalities in the brain such as arterial stenosis, arterial-venous malformations, arteriovenous fistulas, cavernous angiomas, and brain aneurysms. When DSA is performed, heparin is used to prevent a blood clot or thrombus from forming in the blood vessels of the brain. The DSA is intended as a diagnostic procedure.

The Intra-Arterial Heparin Flushing medical procedure uses a modified Digital Subtraction Angiography (DSA) instrument to observe the patient's motor function. After DSA is completed, the procedure continues with the administration of heparin into the blood vessels to improve motor function.¹⁹ It was also mentioned that IAHF therapy has a good effect on stroke conditions through a combination of four effects, namely; antegrade flow, retrograde flow, collateral flow and anti-inflammatory heparin. The three flow effects result from the combined thrombolytic effect of heparin, hydrostatic pressure, and mechanical pressure of the spray. This still requires theoretical study due to the differences between blood vessels in the brain and other systemic blood vessels in the body. The brain artery wall consists of three concentric layers: the innermost layer is the tunica intima, which consists of a single layer of endothelial cells and internal elastic lamina (IEL); the next layer is the tunica media, which contains mostly smooth muscle cells with some elastin and collagen fibers; and the outermost layer is the tunica adventitia. This still requires theoretical study due to the differences between blood vessels in the brain and other systemic blood vessels in the body. The brain artery wall consists of three concentric layers: the innermost layer is the tunica intima, which consists of a single layer of endothelial cells and internal elastic lamina; the next layer is the tunica media, which contains mostly smooth muscle cells with some elastin and collagen fibers; and the outermost layer is the tunica adventitia. Unlike the systemic arteries, cerebral arteries do not have an external elastic lamina. Another difference between cerebral arteries and other systemic

18 I Gede Agus Kurniawan, Ade Chandra., The Civil Law Aspects of Informed Consent to Medical Procedures, *SASI* 30, Issue. 3, (September 2024): 326 - 338

19 Z Ningsih, L Hakim and I B Prayogi., Fluid Dynamic Analysis of IAHF (Intra Arterial Heparin Flushing) Stroke Therapy in Microfluidic Channel. *Journal of Physics: Conference Series* 1430, No. 1 (2020): 1-6

arteries is the lack of elastic fibers in the medial layer and the very thin adventitia layer, which is small and fragile, so it is easy to rupture and can result in extensive bleeding in the brain and cause death. The main point of the objection is that in this case heparin was used for a different purpose than it was intended to be used for, so it is necessary to test the efficacy of heparin in the IAHF procedure.

Heparin works by enhancing the effect of the serine protease inhibitor antithrombin which is heparin's main cofactor in inhibiting thrombin and other coagulation proteases, especially factors Xa and IIa.²⁰ Heparin binds to the AT enzyme inhibitor through the highly affinity pentasaccharide sulfate sequences present in the heparin polymer. In addition, heparin must bind to coagulation enzymes and antithrombin to inhibit thrombin. The complex between thrombin, antithrombin, and heparin will cause inactivation of procoagulant enzymes thereby inhibiting thrombin formation. When proteases are activated, heparin that binds to antithrombin will be released so that it can bind again to other free serpins. Heparin does not have a fibrinolytic effect so it cannot break up blood clots that have already formed.²¹

The Cerebral Intra-Arterial Heparin Flushing procedure was originally intended as an alternative therapy for acute ischemic stroke. The method used in brainwashing is DSA plus the medical procedure IAHF as a therapeutic effort. They considered IAHF as a new way to reduce the disability of stroke patients. Unlike acute ischemic stroke, there is no universally agreed guideline on the management of chronic ischemic stroke. Several studies have been conducted in various ways, but no evidence-based studies have been approved. The above medical procedure is still too far away to be established as a standardized medical procedure and certainly should not be commercialized because it does not have evidence base medicine. However, without being preceded by in-depth studies, this procedure has been directly applied in the community.

2. An Ethical Aspects of Non-Evidence Based Medical Procedures

Ethics is closely related to professionalism.²² Professionalism requires a professional to behave in accordance with the standards of the profession. But the reality is that most medical professionals today have neglected the obligations of the profession as a group dedicated to a moral community based on the primacy of ethical obligations to the sick instead of prioritizing personal interests and market interests.

20 Danielle M (etc)., The Anticoagulant and Nonanticoagulant Properties of Heparin, *Thrombosis and Haemostasis* 120, No. 10 (2020): 1371-1383

21 Hirsh J, Anand SS, Halperin JL, Fuster V., Mechanism of action and pharmacology of unfractionated heparin. *Arterioscler Thromb Vasc Biol* 21, No. 7 (2001): 1094-1996.

22 Herrera Horta (etc)., Thics in The Professional Practice Of Imaging Specialists, *Seminars in Medical Writing and Education* 2, (2023): 1-6

Ethics and law are two very productive and coinciding disciplines.²³ Both are normative in that they determine how things ought to be.²⁴ In this conception, ethics is at the level of norms and principles, thus the position of ethics is above the law. The implication is that a violator of ethics will sociologically receive more blame than a violator of the law, including the law.

Ethical violations and ethical enforcement in democratic countries and their laws have been integrated into the life of the nation, state and society,²⁵ so ethical violations usually have implications equivalent to violations of the law, such as examples in Japan and China. Many state officials in these countries have chosen to resign from their positions because they have been proven or even just suspected of committing ethical violations.

This is very different in our country where almost every time we see someone who is clearly and obviously guilty, but has to be released because of inadequate formal legal procedures and even because of the inability of the judiciary to touch people who have power, in the form of power or money. Therefore, their respect for human dignity is valued less than mere position.

Doctors as health providers have public commitments and promises.²⁶ Universal values that have been established can be landed in the life of the Indonesian nation and then also applied as basic moral rules or bioethical basic rules that are used as a frame for ethical norms carried out by doctors every day.

The World Medical Association has therefore developed the International Code of Medical Ethics as a canon of ethical principles for members of the medical profession worldwide. The code defines and explains the professional obligations of doctors towards their patients, towards other health professionals, towards themselves, and towards society as a whole. Physicians should be aware of applicable national ethical, legal and regulatory norms and standards as well as relevant international standard norms.²⁷

Currently, the medical procedure of IAHF as a therapy is not yet known whether it is a service-based medical procedure or a routine service performed commercially. However, according to Arif Kurniawan et al stated that IAHF has been studied in a randomized clinical trial, is valid

23 Van Der Burg, W., *Law and Ethics: The Twin Disciplines, Erasmus Working Paper Series on Jurisprudence and Socio-Legal Studies*, No. 10-02 (2010): 1-27

24 Martin L Cook., *Reflections On The Relationship between Law and Ethics. Adelaide Law Review* 40, No. 2 (2019): 485-504

25 Udiyo Basuki and Rudi Subiyakto., *77 Tahun Negara Hukum: Refleksi atas Dinamika Politik Hukum dalam Tata Hukum Menuju Masyarakat Hukum Indonesia yang Demokratis, Supremasi Hukum* 11, No. 2 (2022): 179-202

26 Aco Dahrul Saharuddin., *Peningkatan Pelayanan Kesehatan Masyarakat Sebagai Implikasi Kinerja Pegawai Di Puskesmas Tammero'do Kecamatan Tammero'do Kabupaten Majene, MITZAL: Jurnal Ilmu Pemerintahan & Ilmu Komunikasi* 2, No. 1 (2017): 93-106

27 Ramin Walter Parsa-Parsi., *The International Code of Medical Ethics of the World Medical Association, Jama* 328, No. 20 (2022).

and the level of evidence includes Level B. The action of IAHF is in the medium recommendation class based on research 1) randomized clinical trials and 2) observations with large samples assessed based on exposure to sample numbers.

Clinicians should exercise caution in discussing new discoveries, technologies or treatments in non-professional, public environments, including social media, and should ensure that their statements are scientifically accurate and understandable. Doctors should also be able to point out when their own opinions may at times conflict with evidence-based scientific information. Medical research involving human subjects should be in accordance with generally accepted scientific principles, based on a thorough knowledge of the scientific literature other relevant sources of information and adequate laboratories.

The research protocol must be submitted to the ethics committee for consideration, comments, guidance and committee approval. Ethics committee approval should be sought for any medical research conducted in the educational process at any level of medical education. The ethics committee must be transparent and independent. Meanwhile, researchers must be able to avoid the influence of sponsors and other undue influences.

In the treatment of a patient, where scientifically proven interventions are not available and other available interventions are known to be ineffective, the physician, after seeking expert advice and with the consent of the patient or the patient's legally authorized representative, may utilize non-evidence-based interventions, if in the physician's judgment these offer hope of saving life, restoring health, or alleviating suffering. These therapies must then be the object of research, designed to evaluate their safety and efficacy. In all medical cases, new information should be recorded and published.

Referring to the articles of the international code of ethics and the Declaration of Helsinki issued by the World Medical Association, it can be said that if IAHF as a therapy is a research, as expressed by Arif Kurniawan et al, then it can be said that the medical procedures of IAHF as therapy cannot be accounted for according to scientific principles, violating international ethics, and violating international research rules contained in the Declaration of Helsinki.

Therefore, ethical and disciplinary bodies need to be alert to hold accountable medical practitioners who conduct research or services that are not in accordance with the principles of evidence-based practice because such actions are unprofessional and have serious disciplinary consequences.

3. Legal Aspects of Non-Evidence Based Medical Procedures

Legal Protection consists of two words, namely protection and law. Protection is a series of activities to guarantee and protect someone. Meanwhile, the law is a whole of rules that must be obeyed by everyone and for those who violate it are subject to sanctions. So the law is made

with the aim of creating peace and providing protection and security to the subject and object of law.²⁸

A fundamental aspect of the doctor-patient relationship is the ethical obligation to maintain the confidentiality of all patient information.²⁹ The doctor's profession is more of a humanitarian vocation by prioritizing the safety and interests of patients and not prioritizing personal interests. For this reason, a doctor in carrying out his task has a noble reason, namely trying to preserve the patient's body in good health and trying to make the patient's body healthy, or at least reduce the patient's suffering.

But that the health service efforts made by a doctor to a patient do not always work well because there are times when these efforts fail, so that the patient becomes a casualty. Conditions like this by the public tend to link the doctor's mistakes with violations of the law. This brings concerns for doctors in running their profession. This concern can be understood as a vigilance in practicing medicine, because there is legal protection for a doctor who is practicing his profession. People who think that mistakes in performing the doctor's profession should be subject to criminal sanctions are not entirely correct.

The existence of claims of mistakes in practicing the doctor's profession will be studied by an ethics panel and a disciplinary panel formed by the Ministry of Health which will ultimately make a decision and issue a recommendation whether the medical / health worker has committed unlawful acts / actions in performing health services and will be held accountable for adverse health service actions / actions in accordance with PP No. 28 Article 713 letter e.

If the prosecution is filed through a law enforcement agency, namely the police, an investigation will be carried out immediately. If the results of the investigation turn out to be insufficient evidence that the case submitted is not a criminal offense and the doctor's mistake falls within the scope of violations of the Code of Ethics and Discipline, then the investigator with a determination letter will stop the investigation. This is in line with Government Regulation No. 28 Year 2024 article 723.

In a situation where a doctor provides medical services that are not in accordance with Standard Operating Procedures (SOP), Professional Standards, Minimum Service Standards (SPM), or National Medical Service Guidelines (PNPK) and causes harm to patients, this becomes a serious issue in world of law. Patients who become victims in this case usually experience permanent disability or even die due to medical practices that do not meet the main standards, namely evidence-based medical practices.³⁰ This concept forms the basis of legal analysis

28 M. Nurdin., *Perlindungan Hukum Terhadap Pasien Atas Korban Malpraktek Kedokteran. Jurnal Hukum Samudra Keadilan* 10, Issue 1 (2015): 92-109

29 Ta Larasati, (etc)., *The Ethical and Legal Aspects of Health Policy on Electronic Medical Records in Indonesia, Cepalo* 8, No. 2 (July 2024): 103-122

30 Bambang Tri Bawono., *Legal Protection Of Doctors In Providing Health Services, IJLR: International Journal of Law Reconstruction* 4, No. 1 (2020): 24-33

of evidence-based medical procedures. In carrying out their profession, a doctor is required to always act ethically, which means the legal system must also be enforced based on moral and ethical values. Law has the aim of safeguarding the interests of the wider community, not just the interests of a certain group of people in order to protect their rights.

Referring to Law No. 17 of 2023, specifically Article 308 paragraphs (1) and (2), it is regulated that medical or health personnel who are suspected of committing unlawful acts in providing health services which may be subject to criminal sanctions, must first obtain a recommendation from assembly as intended in Article 304. In addition, if medical or health personnel are held civilly responsible for actions that harm patients related to health services, a recommendation from the same assembly is also required. This shows that there is a legal protection mechanism which aims to ensure that any accusations against medical personnel are not carried out arbitrarily, but rather through appropriate procedures.³¹

Furthermore, in Law No. 1 of 2023 or the 2023 Criminal Code, Article 474 regulates criminal sanctions for every person whose negligence causes injury to another person, resulting in illness or obstruction of a person in carrying out their work or profession for a certain period of time. The punishment imposed is a maximum imprisonment of one year or a category II fine. If this negligence causes serious injury, the sanction imposed is imprisonment for a maximum of three years or a category III fine. If the negligence causes death, then the criminal threat is imprisonment for a maximum of five years or a category V fine. In Article 475, it is stated that if the criminal act is committed in the context of carrying out duties, work or profession, then the penalty can be increased by one third of the criminal threat. applies. In addition, the perpetrator may be subject to additional punishment in the form of announcing the judge's decision and revoking certain rights.

In civil law, the Civil Code also provides a legal basis through Article 1365 which states that every unlawful act that causes loss to another person requires the perpetrator to compensate for the loss. Article 1366 adds that a person is responsible not only for losses caused by his own actions, but also for his negligence or lack of care. Meanwhile, Article 1367 states that a person is also responsible for losses caused by the actions of people under his or her care or objects under his or her supervision.

4. Relevance of IAHF as a therapy on Legal Aspects of Evidence-based Medical Procedures

According to Hermien, professional standards are the intentions or good intentions of doctors based on the professional code of ethics,

31 Gunawan Widjaj., Law No.17/2023 concerning Health Does Not Recognize Acts Against Civil Law in Medical/Health Malpractice. *International Conference on Science, Innovations and Global Solutions*, (2024): 379-384

based on agreement or approval from professional doctors to determine which actions can be taken or actions that cannot be taken in carrying out practice. Professional standards are a measure of doctor's actions that have been approved by professional doctors. Because doctors in practicing their profession need to adhere to three general measures, namely authority, expertise and general accuracy.³²

In any cerebral DSA procedure, heparin is used to reduce the formation of thrombotic layers, and prevent thromboembolic complications. In the medical procedure of IAHF as a therapy, heparin is sprayed which has a favorable effect on the cerebral blood vessels of stroke patients. This is described as cleaning a clogged sewer drain. The heparin liquid used in the IAHF procedure is believed to be effective for: 1) Destroying blood clots; 2) Prevent blood clots; 3) Unblock blood vessels; and 4) Reduce the size of blood clots.

However, according to Machfoed, there is no reference that cerebral angiography using heparin can be used for the management of both acute and chronic ischemic stroke. Heparin's biological mechanism is unable to destroy blood clots that occur in acute and chronic ischemic stroke. This is corroborated by Eriksson who concluded that there is no new scientific information or national clinical practice guidelines that use heparin as a treatment for progressive ischemic stroke.³³ For this reason, IAHF medical procedures are not universally evidence-based for approval, despite improved clinical outcomes.

Therefore, medical procedures that are in accordance with evidence-based medicine are ethical decisions because they are performed by humans on other humans, and the treatments provided are those that have been proven to provide the best results. In contrast to evidence-based medicine, unorthodox medical procedures that are not guided by the scientific principles of modern medicine and are based solely on testimonials are not only likely to provide no benefit to the patient and may cause significant harm. This is also a disaster for the rules of ethics, the rules of science, and the rules of scientific methods that can lead to a humanitarian disaster if medical practices that are not evidence-based are continued.

Hospitals that provide research-based services should form an independent supervisory team that is determined by a decree of the hospital director. The independent supervisory team as intended consists of relevant experts from internal and external to the hospital, then this team will report its findings to the hospital director. The Ministry of Health as the implementing agency in the field of public health should not ignore this condition.

32 Sapta Aprilianto., Peran Majelis Kehormatan Disiplin Kedokteran Indonesia (MKDKI) Terhadap Dugaan Kelainan Medis Dokter. *Yuridika* 30, No. 3 (2015): 435.

33 Marie Eriksson (etc.), Discarding heparins as treatment for progressive stroke in Sweden 2001 to 2008, *Stroke* 41, No. 11 (2010): 2552-2558.

The novelty of this research is the exploration of the Cerebral Intra-Arterial Heparin Flushing (IAHF) procedure as a medical innovation that modifies Digital Subtraction Angiography (DSA) for stroke therapy, although it does not yet have sufficient scientific validation. This discussion highlights a major gap in evidence-based medicine, where experimental procedures such as IAHF have been implemented directly without comprehensive studies, thereby posing ethical, legal, and professional challenges in the medical world. By examining the fundamental differences between the fragile structure of the cerebral vasculature and the systemic vasculature, this discussion provides new insight into the unique risks posed by the use of heparin in stroke therapy. In addition, there is the relevance of integrating ethics, law and professionalism in developing medical procedures based on research, as well as ensuring patient protection and public trust. It is recommended to medical professionals that in practicing their profession they must comply with standards, carry out evidence-based medical practice, in order to avoid violations of the law that must be accounted for when facing ethicomedicolegal issues that are not in accordance with the standards set by law.

D. CONCLUSION

DSA Medical Procedures do not violate professional discipline if the purpose is carried out as a diagnostic effort, but if the purpose is as a therapeutic effort - the modification of DSA which is named as the IAHF medical procedure as a stroke prevention therapy certainly violates professional discipline. IAHF medical procedures that function as therapy have not followed scientific principles, scientific methods, international ethics, and the Declaration of Helsinki as requirements that must be met. If these services continue to be carried out commercially while IAHF medical procedures are not evidence-based, this is a violation of ethics, professional discipline and law. The legal construction is Law No. 17 of 2023 article 308 paragraph 1 and 2; In Law No. 1 of 2023 or the Criminal Code (KUHP) 2023 in article 51 letter a, namely article 474, Article 475 Civil Code (KUHP) Article 1365, Article 1366 and Article 1367. It is recommended to medical professionals that in practicing their profession they must comply with standards, carry out evidence-based medical practice, in order to avoid violations of the law that must be accounted for when facing ethicomedicolegal issues that are not in accordance with the standards set by law.

BIBLIOGRAPHY

Books:

- DI Sackett (etc)., *Evidence-Based Medicine. Evidence Based Medicine-How to Practice and Teach EBM. 2nd Edition*, Churchill Livingstone, London, 2000.
- Freckelton Sc, I., *Evidence-based medicine and the law. Legal and Forensic Medicine*. 2013.

Journals:

- Aco Dahrul Saharuddin., Peningkatan Pelayanan Kesehatan Masyarakat Sebagai Implikasi Kinerja Pegawai di Puskesmas Tammero'do Kecamatan Tammero'do Kabupaten Majene, *MITZAL: Jurnal Ilmu Pemerintahan & Ilmu Komunikasi* 2, No. 1, (2017).
- Arief Budiono (etc)., Black Swan Theory: Legal Policy of the Indonesian National Healthcare, *Legality: Jurnal Ilmiah Hukum* 30, No. 1, (March 2022).
- Arief Kurniawan and Nur Pudyastuti Pratiwi., Kontroversi Terapi Dsa Pada Gangguan Vaskuler Otak, *Journal of Innovation Research and Knowledge* 1, No. 11, (April 2022).
- Bambang Tri Bawono., Legal Protection of Doctors In Providing Health Services, *IJLR: International Journal of Law Reconstrction* 4, No. 1, (2020).
- Bas de Boer and Olya Kudina., What Is Morally at Stake When Using Algorithms to Make Medical Diagnoses? Expanding The Discussion Beyond Risks and Harms, *Theor Med Bioeth* 42, (2021).
- Danielle M (etc)., The Anticoagulant and Nonanticoagulant Properties of Heparin, *Thrombosis and Haemostasis* 120, No. 10, (2020).
- Frederic W. Hafferty and Donald W., Light, Professional Dynamics and the Changing Nature of Medical Work, *Journal of Health and Social Behavior*, (1995).
- Gunawan Widjaja., Law No.17/2023 concerning Health Does Not Recognize Acts Against Civil Law in Medical/Health Malpractice, *International Conference on Science, Innovations and Global Solutions*, (2024).
- Herrera Horta (etc)., Thics in The Professional Practice of Imaging Specialists, *Seminars in Medical Writing and Education* 2, (2023).
- Hirsh J, Anand SS, Halperin JL, Fuster V., Mechanism of action and pharmacology of unfractionated heparin, *Arterioscler Thromb Vasc Biol* 21, No. 7, (2001).
- I Gede Agus Kurniawan, Ade Chandra., The Civil Law Aspects of Informed Consent to Medical Procedures, *SASI* 30, Issue. 3, (September 2024).

- M. Nurdin., Perlindungan Hukum Terhadap Pasien Atas Korban Malpraktek Kedokteran. *Jurnal Hukum Samudra Keadilan* 10, Issue 1. (2015).
- Marie Eriksson (etc), Discarding heparins as treatment for progressive stroke in Sweden 2001 to 2008, *Stroke* 41, No. 11, (2010).
- Martin L Cook., Reflections On the Relationship between Law and Ethics. *Adelaide Law Review* 40, No. 2, (2019).
- Moh Hasan Machfoed (etc)., Does Intra-Arterial Heparin Flushing (IAHF) Can Actually Increase Manual Muscle Test (MMT) Score in Chronic Ischemic Stroke Patients? *Folia Medica Indonesiana* 52, No. 2, (2016).
- Moh. Mujibur Rohman (etc)., Methodological Reasoning Finds Law Using Normative Studies (Theory, Approach, and Analysis of Legal Materials), *MAQASIDI: Jurnal Syariah dan Hukum* 4, No. 2, (December 2024).
- Muas Mubarak, Didit Darmawan and Rio Saputra., Legal and Ethical Arrangements for Medical Record Filling by Doctors: A Normative Study, *Bulletin of Science, Technology and Society* 2, No. 1, (2023).
- Nadya Adianie and Gunawan Djajaputra., Illegal and Unauthorized Medical Treatment In Therapeutic Transactions, *UNES Law Review* 6, No. 4, (2024).
- Ramin Walter Parsa-Parsi., The International Code of Medical Ethics of the World Medical Association, *Jama* 328, No. 20, (2022).
- Sapta Aprilianto., Peran Majelis Kehormatan Disiplin Kedokteran Indonesia (MKDKI) Terhadap Dugaan Kelalain Medis Dokter. *Yuridika* 30, No. 3, (2015).
- Swanson, J. A., Schmitz, D., & Chung, K. C., How to practice evidence-based medicine. *Plastic and Reconstructive Surgery* 126, No. 1, (2010).
- Ta Larasati (etc)., The Ethical and Legal Aspects of Health Policy on Electronic Medical Records in Indonesia, *Cepalo* 8, No. 2, (July 2024).
- Terawan Agus Putranto (etc)., Intra Arterial Heparin Flushing Increases Cerebral Blood Flow in Chronic Ischemic Stroke Patients, *The Indonesian Biomedical Journal* 8, No. 2, (August 2016).
- Tunggul Ansari Setia Negara., Normative Legal Research in Indonesia: Its Origins and Approaches, *ACLJ: Audito Comparative Law Journal* 4, Issue. 1, (2023).
- Udiyo Basuki and Rudi Subiyakto., 77 Tahun Negara Hukum: Refleksi atas Dinamika Politik Hukum dalam Tata Hukum Menuju Masyarakat Hukum Indonesia yang Demokratis, *Supremasi Hukum* 11, No. 2, (2022).

Van Der Burg, W., *Law and Ethics: The Twin Disciplines, Erasmus Working Paper Series on Jurisprudence and Socio-Legal Studies*, No. 10-02, (2010).

Z Ningsih, L Hakim and I B Prayogi., Fluid Dynamic Analysis of IAHF (Intra Arterial Heparin Flushing) Stroke Therapy in Microfluidic Channel. *Journal of Physics: Conference Series* 1430, No. 1, (2020).

Regulations:

Law No. 17 of 2023 on Health

Law No. 29 of 2004 on Medical Practice

Law No. 36 of 2009 on Health

Minister of Health Regulation No. 1438 of 2010 Concerning Health Service Standards.