Juridical Review of Medical Devices in Legal Regulation, Hospital Accreditation, and ISO Management System at RSPAD Gatot Soebroto

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Abstract. The use of medical devices according to standards will improve the quality of health services for the community. Quality health services have implications for improving the quality of life of the community. This study analyzes the feasibility of using medical devices in terms of legal regulations, hospital accreditation and the use of the Domestic Content Level (TKDN). This research uses a qualitative approach with the case study method as a strategy of inquiry. Primary data collection was conducted by in-depth interviews and observations. While secondary data were collected through document studies and analyzed with qualitative data findings intensively. The results of this study show that the use of medical devices in accordance with legal regulations, hospital accreditation and using and paying attention to medical devices with TKDN have implications for quality health services among patients at RSPAD Gatot Subroto hospital.

Keywords: RSPAD Gatot Soebroto, Juridical Review, Medical Devices.

1 Introduction

The Dutch colonial government established the Groot Militair Hospitaal Weltevreden in October 1936, which served as a precursor to the RSPAD Gatot Soebroto Army Central Hospital. Alongside its ongoing presence, Gatot Soebroto Medical clinic has turned into a kind An administration clinic and is the most noteworthy reference in the positions of the TNI overall and the Military specifically, which is likewise a wellbeing administration for the overall population. RSPAD Gatot Soebroto is a carrying out component at the Military Base camp (Mabesad) level which is straightforwardly under the Head of Staff of the Indonesian Armed force (Kasad) which has the principal assignment of giving the most elevated wellbeing administrations in the positions of the TNI to help the obligations of the Indonesian Armed force. Aside from being the most elevated reference medical clinic in the positions of the TNI, Gatot Soebroto Emergency clinic is additionally the really official reference clinic. Gatot Soebroto Clinic, as well as being broadly and universally certify, is likewise assigned as a PK-BLU emergency clinic which has the primary undertaking of giving total wellbeing administrations to VVIPs, warriors and government workers and their families and is directed by pertinent regulations and guidelines to further develop administration quality and patient security.

The vision of Gatot Soebroto Clinic is to turn into an official standard emergency clinic, which is the pride of troopers, the TNI family and the local area. In the interim, the

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missions of RSPAD Gatot Soebroto, among others: (a) Putting together the best medical care for the President, Vice President, and their families, as well as former presidents and vice presidents and their families and state visitors; (b) Coordinating the most noteworthy whole and reference emergency clinic administrations for Warriors, TNI More distant family, High State Authorities and the Local area; (c) Putting together the Public Wellbeing Framework through worldwide standard medical clinic administrations; (d) Offering elite phenomenal types of assistance; also (e) Work on the capacity of wellbeing laborers through instruction and preparing and foster prevalent exploration based administrations.

Gatot Soebroto Hospital, which was built on 12.5 hectares of land and has a building area of 115,010 m2, has adequate facilities and infrastructure to accomplish the aforementioned vision and mission. One of these is the installation of a material warehouse to store health supplies in accordance with Law No. 36 of 2009 concerning Wellbeing.[1] In article 1 section 3 of Law of the Republic of Indonesia Number 36 of 2009 concerning Wellbeing, it is expressed that wellbeing supplies are materials and gear expected to complete wellbeing endeavors. Wellbeing endeavors themselves are any exercises and additionally series of exercises did in a coordinated, coordinated and reasonable way to keep up with and work on the level of general wellbeing as illness avoidance, wellbeing improvement, sickness therapy, and wellbeing recuperation by the public authority or potentially the local area. Because of this, Gatot Soebroto Hospital always provides medical supplies that are typically housed in material warehouse installations. The establishment of the material stockroom at Gatot Soebroto Emergency clinic comprises of an overall material distribution center and a wellbeing material stockroom.

Related to the above, Gatot Soebroto Hospital has a commitment to providing health services, especially in terms of medical devices. In article 1 section 3 of Law of the Republic of Indonesia Number 36 of 2009 concerning Wellbeing, it is expressed that wellbeing supplies are materials and gear expected to complete wellbeing endeavors. Wellbeing endeavors themselves are any exercises and additionally series of exercises did in a coordinated, coordinated and reasonable way to keep up with and work on the level of general wellbeing as illness avoidance, wellbeing improvement, sickness therapy, and wellbeing recuperation by the public authority or potentially the local area, tools, and/or implants, in vitro reagents and calibrators, software, materials or materials used single or in combination, to forestall, analyze, fix, and ease illnesses, treat wiped out individuals, reestablishing wellbeing in people, and additionally organizing and further developing body capabilities, obstructing preparation, sanitization of clinical gadgets, and in vitro testing of examples from the human body, and may contain drugs that don't accomplish essential activity in the human body through pharmacological, immunological or metabolic cycles to help the ideal capability/execution.

In addition, there must be a significant amount of domestic content in medical devices and in vitro diagnostic medical devices—the Domestic Component Level, also referred to as TKDN in this document. Connected with TKDN, this is managed in the Guideline of the Clergyman of Industry Number 31 of 2022 concerning Arrangements and Strategies for Ascertaining the Worth of Homegrown Part Levels of Clinical Gadgets and In Vitro Demonstrative Clinical Gadgets. This TKDN plans to help the improvement of the clinical gadget industry and the homegrown in vitro analytic clinical gadget industry in further developing general wellbeing security.

Based on the above, the author intends to conduct a juridical review of the feasibility of medical devices in legal regulations, hospital accreditation, and ISO management systems at Gatot Soebroto Hospital. In this paper, juridical review can be interpreted as a rigorous examination activity, data collection or investigation carried out systematically and objectively on something according to or based on laws and regulations.[2] The Law of the Republic of

Indonesia Number 36 of 2009 about Wellbeing and Guideline of the Clergyman of Strength of the Republic of Indonesia Number 54 of 2015 concerning Testing and Adjustment of Clinical Gadgets are connected with the subject of writing in this legal audit.[3] In addition to the review in legal aspects, the author also conducts a review in the aspect of hospital accreditation as per the Declaration of the Pastor of Strength of the Republic of Indonesia Number Hk.01.07/Menkes/1128/2022 concerning Emergency clinic License Guidelines and ISO 13485 concerning medical equipment quality management systems.[4]

2 Method

The sort of lawful examination utilized is regulating legitimate exploration. Regulating legitimate examination is lawful exploration led by inspecting optional writing or information.[5] In this kind of legitimate examination frequently the law is conceptualized as what is written parents in law and guidelines (regulation in book) or regulation is conceptualized as decides or standards that are a benchmark for human way of behaving that is viewed as proper. What's more, this review involves a legal methodology which in this review centers around Law of the Republic of Indonesia Number 36 of 2009 concerning Prosperity, and Rule of the Cleric of Sufficiency of the Republic of Indonesia Number 54 of 2015 concerning Testing and Arrangement of Clinical Contraptions. Notwithstanding the survey in legitimate perspectives, the creator likewise directs an audit in the part of medical clinic certification as per the Declaration of the Clergyman of Soundness of the Republic of Indonesia Number Hk.01.07/Menkes/1128/2022 concerning Hospital Accreditation Standards and ISO 13485 concerning medical equipment quality management systems.

In view of the kind of lawful exploration utilized is regularizing legitimate examination, the exploration information that is referred to in this study is Auxiliary Information, to be specific as Essential Lawful Material and Optional Lawful Material.[6] Essential legitimate material is lawful material that is definitive, which has authority, which incorporates regulation, official records or minutes in settling on regulation and judges' choices.[7] While auxiliary legitimate materials are obtained from lawful and non-lawful sentiments from writing, research results connected with data acquired from the speakers. The utilization of optional lawful material is to furnish specialists with a sort of "hint" in which heading the examination is heading. Then, at that point, for the information examination strategy in this composing applies five errands of obdurate regulation or legitimate science from a tight perspective that spotlights on sure regulation, specifically regulations and guidelines which incorporate, depiction, systematization, investigation, understanding and appraisal of positive regulation and assessment to answer issues.[8]

3 Results and Discussion

3.1 Implementation of Regulation of the Minister of Health of the Republic of Indonesia Number 54 of 2015 concerning Testing and Calibration of Medical Devices

Medical device technology currently has excellent capabilities and quality, so that various kinds of health problems can be detected using these medical devices. But. No matter how good the quality of the medical device is, it does not mean that the tool always works optimally. There is a need for maintenance, testing and calibration of medical devices to improve the accuracy of these medical devices.

In view of Regulation No. 36 of 2009 concerning Wellbeing, it gives everybody the option to get protected, quality, and reasonable wellbeing administrations. To improve the quality and safety of health services, it is necessary to provide quality medical devices, namely medical devices that are guaranteed accuracy, accuracy and safety of their use. Medical devices must have strict *performance*, including *accuracy*, sensitivity, *reproducibility and safety aspects*. So that in its use it will always be ready to use and have technical standards for the use of medical equipment.

The gamble of clinical gadgets that are not tried or aligned, has an inappropriate result that will cause less exact indicative outcomes and helpful portions. Essentially, clinical gadgets that are not utilized for a specific timeframe and have never been done upkeep cause a reduction in the degree of dependability, wellbeing isn't ensured and the state of the hardware isn't controlled.

In connection with global demands in the quality of health services, the existence of Law No. 8 of 2009 concerning Consumer Protection,[9] medical devices used in Health Service Facilities so as not to risk harming recipients of health services must be tested and / or calibrated periodically according to the type of medical device.

As per Unofficial law Number 60 of 2008 concerning the Public authority Interior Control Framework (SPIP) article 11 has given a firm command that in an administration framework there is a requirement for a powerful government interior oversight contraption and Guideline of the Clergyman of Soundness of the Republic of Indonesia Number 54 of 2015 concerning Testing and Alignment of Clinical Gadgets article 4 section (1), article 6 passage (1), (2), (3) and article 9 sections (1), (2) have expressed that:

- Article 4 paragraph (1):
  " *Each Clinical Gadget utilized in Wellbeing Administration Offices and other Wellbeing Offices should be tried and additionally adjusted occasionally by the Wellbeing Office Testing Center or Wellbeing Office Testing Establishment*."

  In the article and paragraph above, every health service facility and other health facilities in this case Gatot Subroto Hospital must test and / or calibrate every medical device that will be used in providing health services. In this context, RSPAD Gatot Subroto before using medical devices first asks for a license for the test and calibration of medical devices from medical device providers.

- Article 6 paragraph (1):
  " *Testing of Medical Devices in Health Care Facilities and other Health Facilities includes function tests, safety tests, and performance tests*."

  In the article and paragraph above, medical devices used by Gatot Subroto Hospital carry out tests and / or calibrations of each medical device in the form of function tests, safety tests, and performance tests.

- Article 9 paragraph (1):
  " *Medical Devices that have met the standards based on the results of Testing and/or Calibration, must be given a Certificate and Label of Fit for Use*."

  In the article and paragraph above, Gatot Subroto Hospital has stored certificates and labels of the eligibility of the medical devices used. However, there are still medical devices that do not have certificates and labels of eligibility, but are given a label of

information of unfit for use as stated in article 9 paragraph 2, " *Medical Devices that do not meet the standards based on the results of Testing and / or Calibration, must be given information and labels are not fit to use*."

3.2 Implementation of Hospital Accreditation

A medical clinic is a wellbeing administration organization that gives entire individual wellbeing administrations that give long term, short term, and crisis administrations. In offering types of assistance, emergency clinics should focus on quality and patient security. Quality wellbeing administrations are administrations that have the personality of protected, ideal, productive, viable, patient-arranged, fair and incorporated. Fulfillment of service quality in hospitals is carried out in two ways, namely internal quality improvement and external quality improvement.

Internal Continuous *Quality Improvement*, where the hospital makes periodic quality improvement efforts, including setting, measuring, reporting and evaluating quality indicators and reporting patient safety incidents. This internal quality improvement is the most important thing for hospitals to ensure the quality of service. External *Continuous Quality Improvement* is part of efforts to improve the quality of service in the hospital as a whole. Some activities that include external quality improvement are licensing, certification, and accreditation. Clinic license as per the Declaration of the Priest of Strength of the Republic of Indonesia Number Hk.01.07/Menkes/1128/2022 concerning Clinic Certification Guidelines is an acknowledgment of the nature of clinic administrations after an evaluation is made that the clinic has satisfied the certification guidelines supported by the Public authority.[10]

Related to the components of hospital accreditation, one of them is the quality and quality of medical devices owned by hospitals. In other words, Gatot Soebroto Hospital, which has Plenary accreditation from the Independent Accreditation Assessment Institute (LIPA), namely the Indonesian Health Facility Accreditation Institute (LAFKI), has certainly been declared that the medical devices it uses are in accordance with standards.

3.3 ISO Management System Implementation

ISO certificate is a proof of service in international quality health institutions. So that it can be interpreted, ISO is a recognition from an independent institution for the quality and services produced by hospitals. One of the ISO related to standards on medical equipment quality management systems, namely ISO 13485.

This standard gives a structure to associations to create, execute, screen and consistently further develop clinical gadget quality administration frameworks and consistence with relevant regulations and guidelines and different necessities.

The purpose of ISO 13485 is to produce a safe medical device production process for customers. Through a series of quality standard processes including consistency in design, development, production, installation, and delivery of medical devices to direct customers or distributors. Through ISO 13485, prevention of the release of medical devices and their misuse can be applied. Being ISO 13485 certified means that the hospital has received a globally recognized certificate in the field of medical equipment quality management systems. This proves that the hospital has been able to provide safe and competent medical devices and achieve customer trust.

Related to ISO 13485, based on the results of field research conducted by the author, RSPAD Gatot Soebroto has not implemented an ISO 13485 management system for quality management of medical devices.

4 Conclusion

RSPAD Gatot Soebroto is a type A government hospital that is the highest reference in the ranks of the TNI in general and the Army in particular. It is also a health service for the general public that continues to strive to improve its quality in an effort to provide complete health services for each patient. RSPAD Gatot Soebroto is also a health service for the general public. This effort is certainly one of them followed by quality improvements in the medical devices used. Connected with the Guideline of the Pastor of Strength of the Republic of Indonesia Number 54 of 2015 concerning Testing and Alignment of Clinical Gadgets article 4 passage (1), article 6 section (1), and article 9 passage (1), (2) states that Gatot Soebroto Hospital before using medical devices first asks for a license for the test and calibration of medical devices from medical device providers. In addition, Gatot Subroto Hospital conducts tests and / or calibrations of each medical device in the form of function tests, safety tests, and performance tests. RSPAD Gatot Soebroto has stored certificates and labels of eligibility for the medical devices used. However, there are still medical devices that do not have certificates and labels that are fit to use, but are given information labels that are not fit to use. Related to the components of hospital accreditation, one of them is the quality and quality of medical devices owned by hospitals. In other words, Gatot Soebroto Hospital, which has Plenary accreditation from the Independent Accreditation Assessment Institute (LIPA), namely the Indonesian Health Facility Accreditation Institute (LAFKI), has certainly been declared that the medical devices it uses are in accordance with standards. Related to ISO 13485, based on the results of field research conducted by the author, RSPAD Gatot Soebroto has not implemented an ISO 13485 management system for quality management of medical devices.

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