



Comparative Study on Sectio Caesarean Surgical Wound Infection and Ministry of Health Regulation Implementation

Studi Banding Infeksi Luka Operasi Caesar dan Implementasi Peraturan Kementerian Kesehatan

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Abstract

The global rise in cesarean section (CS) deliveries has increased the risk of surgical site infections (SSI), a leading cause of maternal morbidity and mortality. To address this issue, Indonesia introduced Ministry of Health Regulation No. 40 of 2022, which sets technical standards for hospital buildings, infrastructure, and medical equipment. This study aimed to assess the impact of implementing the regulation on SSI incidence among CS patients by comparing RSU PKU Muhammadiyah Gubug, which has implemented the regulation, and RS Aisyiyah Kudus, which has not. A cross-sectional mixed-methods study was conducted from January to April 2025 involving 41 CS patients (10 at RSU PKU Muhammadiyah Gubug and 31 at RS Aisyiyah Kudus). Quantitative data were analyzed using descriptive statistics and independent-sample t-tests, while qualitative data were obtained through semi-structured staff interviews. Results showed no SSI cases at RSU PKU Muhammadiyah Gubug, while one case (3.23%) occurred at RS Aisyiyah Kudus, with no statistically significant difference ($p = 0.251$). Compliance at RSU PKU Muhammadiyah Gubug was supported by staff training and infrastructure upgrades, whereas RS Aisyiyah Kudus faced financial and resource constraints. Although the difference in SSI incidence was not significant, the findings suggest that regulatory adherence positively contributes to infection prevention. Larger multicenter studies are needed to validate these results and strengthen evidence for long-term infection control strategies.

Kata Kunci:

Persalinan
Sesar;
Infeksi Luka
Operasi;
Peraturan
Menteri
Kesehatan;

Abstrak

Angka persalinan sesar (CS) yang terus meningkat secara global menambah risiko infeksi luka operasi (surgical site infection/SSI), salah satu penyebab utama morbiditas dan mortalitas ibu. Untuk menekan angka tersebut, Indonesia menerbitkan Peraturan Menteri Kesehatan No. 40 Tahun 2022 yang mengatur standar teknis bangunan, prasarana, dan peralatan rumah sakit. Penelitian ini bertujuan menilai dampak penerapan regulasi tersebut terhadap kejadian SSI pada pasien CS dengan membandingkan RSU PKU Muhammadiyah Gubug yang telah menerapkannya dan RS Aisyiyah Kudus yang belum. Studi observasional potong lintang dengan pendekatan campuran dilakukan Januari–April 2025 pada 41 pasien CS (10 di RSU PKU Muhammadiyah Gubug dan 31 di RS Aisyiyah Kudus). Data kuantitatif dianalisis dengan statistik deskriptif dan uji t independen, sementara wawancara semi-terstruktur digunakan untuk data kualitatif. Hasil menunjukkan tidak ada kasus SSI

di RSU PKU Muhammadiyah Gubug, sedangkan satu kasus (3,23%) terjadi di RS Aisyiyah Kudus, dengan perbedaan tidak signifikan secara statistik ($p = 0,251$). Meskipun demikian, kepatuhan penuh di RSU PKU Muhammadiyah Gubug didukung pelatihan staf dan peningkatan infrastruktur, sedangkan RS Aisyiyah Kudus menghadapi kendala biaya dan sumber daya. Temuan ini menegaskan bahwa penerapan regulasi mendukung pencegahan infeksi, namun efektivitas jangka panjang memerlukan budaya organisasi, pendidikan staf, dan penelitian dengan sampel lebih besar.

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INTRODUCTION

Background of the Study

The global trend of cesarean section (CS) deliveries has shown a significant increase in recent years. A study encompassing 168 countries, covering 98.4% of all births worldwide, reported that the global CS rate reached 21% in 2015, doubling compared to the year 2000 with an average annual increase of 4% (Zahroh et al., 2020). According to the World Health Organization (WHO) in 2021, more than one in five births are delivered by CS, with projections estimating this figure to rise to nearly one-third by 2030. In Indonesia, the CS rate has escalated from 1.6% in 1991 to 17.6% in 2017, with the latest data in 2023 indicating a further increase to 25.9% (Betran et al., 2021; Devy et al., 2024). This rise is observed not only in emergency CS but also in elective procedures, regardless of medical indications.

While CS can be life-saving for both mother and infant when appropriately indicated, it carries inherent risks that contribute to increased morbidity and mortality. Short-term complications include postpartum infections, hemorrhage, thromboembolism, and maternal death (Sandall et al., 2018). Among these, surgical site infections (SSI) or infections of the operative area represent the most frequently escalating postpartum infection (Albaharnah et al., 2024). Studies in Indonesian teaching hospitals report SSI incidence rates ranging from 5.6% to 12%, with national data from the Ministry of Health in 2011 indicating SSI occurrence as high as 55.1% in hospitals (Kementerian Kesehatan, 2020). Globally, WHO estimates SSI affects 2–5% of surgical patients annually and accounts for 25% of all nosocomial infections. In Indonesia, infections related to CS contribute to 7.3% of maternal deaths (Mengistu et al., 2023).

SSI not only delays wound healing but also prolongs hospital stays by an average of four days, imposing significant economic and social burdens on patients, including loss of income and increased medical expenses (Costabella et al., 2023). From the hospital perspective, high SSI rates indicate poor quality of care and result in wastage of time, equipment, and resources (Mehtar et al., 2020). Key risk factors include inadequate prophylactic antibiotic administration, non-adherence to operating room hygiene protocols, and suboptimal hospital management (Hassan et al., 2021).

In Indonesia, the Ministry of Health Regulation No. 40 of 2022 was introduced to set comprehensive technical requirements for hospital buildings, infrastructure, and medical equipment (Kemenkes RI, 2022). This regulation seeks to enhance patient safety and infection control by enforcing uniform standards across healthcare facilities (Trisaksono et al., 2023). Despite its recent implementation, there is limited empirical

evidence evaluating its impact on clinical outcomes such as the incidence of SSIs in CS patients (Sartelli et al., 2020).

Previous studies have demonstrated that compliance with technical standards in hospital environments correlates with reduced SSI rates (Calderwood et al., 2023; Conoscenti et al., 2025). However, many investigations have focused on individual components such as ventilation systems or sterilization protocols, rather than the holistic application of regulatory frameworks encompassing buildings, infrastructure, and equipment (As & Bilir, 2024; Juhari et al., 2024). Moreover, the socio-organizational aspects influencing the implementation of such regulations—such as staff training, resource allocation, and institutional culture—are often underexplored (Cao et al., 2025; Tang et al., 2025).

A notable research gap exists in evaluating the real-world effectiveness of Ministry of Health Regulation No. 40 of 2022, particularly through mixed-method approaches that combine quantitative infection incidence data with qualitative insights from hospital staff. Understanding both the measurable outcomes and the contextual challenges or facilitators of regulation implementation is crucial for informing policy and practice.

This study aims to fill this gap by comparing the incidence of surgical site infections in cesarean section patients between two hospitals: RSU PKU Muhammadiyah Gubug, which has fully implemented Ministry of Health Regulation No. 40 of 2022, and RS Aisyiyah Kudus, which has not yet adopted the regulation. Utilizing a mixed-methods, observational, descriptive, and cross-sectional design, this research integrates quantitative infection data with qualitative interviews from key informants to provide a comprehensive assessment of the regulation's impact.

The novelty of this study lies in its dual focus on both clinical outcomes and implementation processes within the Indonesian healthcare context shortly after the regulation's enactment. By combining infection incidence analysis with in-depth qualitative data on operational challenges, staff perceptions, and infrastructural adjustments, the study offers valuable insights into the effectiveness and feasibility of regulatory compliance in improving surgical safety. These findings will contribute to evidence-based recommendations for policymakers, hospital administrators, and healthcare workers aiming to optimize infection control strategies in resource-variable settings.

METHODOLOGY

This study applied a mixed-methods design, combining quantitative and qualitative approaches to provide a comprehensive evaluation. The quantitative component employed an observational, descriptive, cross-sectional design using total sampling of cesarean section patients (10 cases at RSU PKU Muhammadiyah Gubug and 31 cases at RS Aisyiyah Kudus). Medical record data were extracted on SSI incidence and analyzed using descriptive statistics and independent-sample t-tests (Shacho et al., 2025).

The qualitative component used semi-structured interviews with hospital staff. To ensure rigor, the interview transcripts were analyzed using thematic analysis (Braun & Clarke, 2006; Castleberry & Nolen, 2018). Two researchers independently coded the transcripts to identify recurring themes related to regulation implementation, compliance, and challenges. Any discrepancies were discussed until consensus was reached, strengthening reliability. Triangulation between quantitative results and qualitative insights enhanced validity and captured the complexity of implementation in real hospital settings (Creswell & Creswell, 2018).

Limitations include:

- Small sample size and low incidence of SSI, limiting statistical power (Wood et al., 2025).
- Cross-sectional design, which cannot establish causal relationships.
- Secondary data reliance, which may reduce accuracy due to record quality.
- Limited generalizability of qualitative findings because of the small number of informants.
- Short-term focus, without assessing long-term patient outcomes or satisfaction (CDC, 2025).

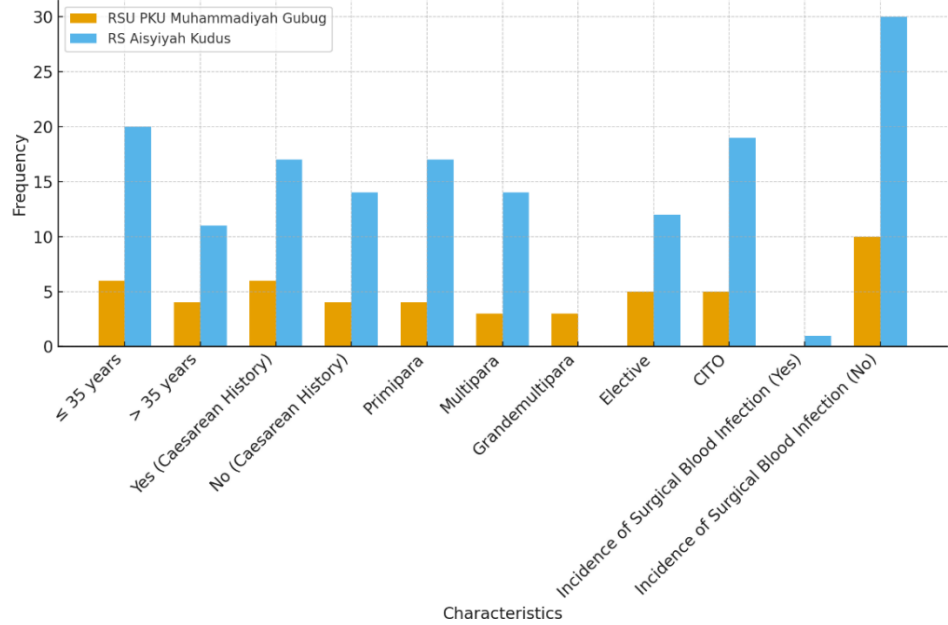
Future studies should adopt larger, multicenter, longitudinal designs and include patient-centered outcomes to strengthen external validity.

RESULT AND DISCUSSION

Result

The following are the results of the distribution of patient characteristics at PKU Muhammadiyah Gubug and RS Aisyiyah Kudus:

Table 1. Characteristic Patient
Comparison of Patient Characteristics Between RSU PKU Muhammadiyah Gubug and RS Aisyiyah Kudus



Based on Table. 1 The results show that at RSU PKU Muhammadiyah Gubug, no SSI cases occurred among 10 patients, while at RS Aisiyiah Kudus, one SSI case (3.23%) occurred among 31 patients. Statistical testing showed no significant difference ($p = 0.251$), likely due to the small sample size.

Compliance with Ministry of Health Regulation No. 40 of 2022 at RSU PKU Muhammadiyah Gubug reached 100% across building, infrastructure, and equipment standards, whereas RS Aisiyiah Kudus had not yet achieved implementation. Interview data confirmed that Gubug hospital benefited from full compliance, including staff training and infrastructure upgrades, while Kudus hospital faced resource and training barriers.

These findings align with broader research showing SSI rates vary widely across settings: 3–20% globally (Shacho et al., 2025) and 2–56% in sub-Saharan Africa (Wood et al., 2025). Overall, the results suggest a positive association between regulatory compliance and reduced SSI incidence, though statistical confirmation requires larger datasets.

Table 2. Calculation Results of Technical Requirements for Hospital Buildings, Infrastructure, and Health Equipment in Ministry of Health Regulation No. 40 of 2022.

Requipements		Indicator Permenkes No. 40 of 2022	Percentage (%)
Item	Indicator		
Hospital Building Standards	Land and Building Access	1. In multi-storey hospital buildings, the location of the operating room is recommended to be on the highest floor, maximum on the 4 th floor. 2. Types of operating rooms in hospitals consist of minor operating rooms, general operating rooms, and major/special operating rooms.	100
	Building Layout	1. The number of action room beds is adjusted to the needs of service capacity. 2. The size of the room per bed is 3x3 m ² , equipped with a dividing curtain. 3. Building materials used must not have a high degree porosity. 4. The design of the operating room layout must meet the provisions of the zone based on the level of sterility of the room consisting of: a. Level sterile zone (normal). b. Medium sterile zone. c. High sterile zone. d. Very high sterile zone.	100
	Total Floor Area Requirement	The area of the Major/Special Surgery Rooms, at least 50 m ² , with a length x width x height of 7.2m x 7m x 3m. The floor-to-floor height in the operating room is at least 4.7 meters, with the following description: 1. Ceiling height from floor 3m. 2. Space above the ceiling for installation of ducting and air conditioning system equipment at least 1.7m.	100

Access Facilities	The operating room must have easy access to the obstetrics and gynecology room, inpatient room, intensive care, emergency room, mortuary, pharmacy room, laundry, sterilization room, radiology room, and other supporting services.	100
Rooms	1. There is an operating room in the hospital. 2. The operating room is equipped with a digital clock. 3. No more than the fourth floor, especially if the Hospital is in a disaster-prone location.	100
Relationship Pattern between Spaces	Located in the yellow zone and separated from other service spaces. Recommended spaces can generally be arranged based on the rules of Infection Prevention and Control (PPI) services.	100
Roof	1. Ceiling materials and hangers must be strong, not falling off during a disaster. 2. Construction for the roof of the operating room uses concrete deck construction.	100
Ceiling	1. The ventilation system in the operating room must be filtered and controlled and separate from other ventilation systems in the Hospital for the sake of infection control and prevention. 2. The ventilation system in the operating room must meet the required parameters of temperature, relative humidity, air cleanliness level, air exchange, room pressure, and air operating distribution. 3. The ventilation system must be separate between one operating room and another operating room. 4. There should be no crossing paths between clean and dirty flow. 5. Staff access to the operating room must be through the dressing room and vice versa. 6. The minimum ceiling height in the operating room must be at least 3.00 m.	100
Walls and Partitions	If it is located in 1 (one) floor building that joins other rooms, then the room must be a single compartment with the requirement that the wall/ partition material has a minimum fire resistance level (TKA) 2 hours.	100
Evacuation Plan	The location of the operating room must be in a quiet, safe, and convenient location.	100

Building Structure	Non-porous building components, viz: 1. Floor covering components must be non-porous, easy to clean, chemical resistant, anti-static, anti-friction, and anti-bacterial. 2. Floor meeting with conical/ curved wall (hospital plant). 3. Fire resistance level of material min. 2 hours. 4. Non-porous wall components, easy to clean, chemical resistant, anti-mold and anti-bacterial. 5. Meeting between wall and conical wall. 6. All wall mounted equipment must be recessed, e.g. movie viewer, wall clock, etc. 7. Non-porous ceiling components, easy to clean, anti-fungal and bacterial, do not have elements that harm patients. 8. Fire Resistance Level (FAR) of ceiling material. 2 hours. 9. All lighting equipment is installed recessed in the ceiling.	100
Bottom Design	All entrance the operating room, viz: 1. Sliding doors with top rails installed on the outside of the room, can be opened and closed automatically with sensors/ steps and can be operated manually in the event of damage. 2. Doors using interlock system. 3. The opening width of the sliding door through which the patient passes is min. 150 cm and min. 85 cm, made of non-porous material, insulated panel system is recommended and painted with anti-bacterial/ fungal paint in light color. 4. The doors are equipped with observation glass. 5. Inter cubical operation room must have a fire resistance level (TKA)	100
Design of Upper Structure	1. In the event that the operating room is integrated with other room must be one compartment. Each operating room is also a separate compartment. 2. The floor above the operating room must be safe from wet areas. 3. The distance between the floor and the floor plate above for the operating room is at least 4.70 meters to meet the needs of mechanical and electrical space.	100

Hospital Infrastructure	Water Supply and Distribution Planning	The provision and distribution of clean water in the Hospital is intended for all operational needs of the Hospital, including building space needs, equipment functions, fire-fighting systems, plant watering and cleaning, the need for Reverse Osmosis, homodialysis services, sterilization machines, operating rooms, laboratories, and other needs.	100
	Reverse Osmosis (RO) Water	The need for special water (reverse osmosis) in hospitals is to meet dialysis services, sterilization machines, scrub up: One hand washing process in scrub up requires 25 liters of RO water. If there are 6 (six) officers in the operating room, then one operation requires 25 liters x 6 = 150 liters of RO water. If in one day there are 6 (six) operations per room, the RO water prepared (including 10% reverse) is (150 liters x 6) x 110% = 990 liters – 1000 liters.	100
	Alarm and Detection System	There is a smoke detector.	100
	Fire Extinguisher	Water mist type class A, B, C.	100
	Sprinkler	Ceiling is not installed sprinkler.	100
	Type of Medical Gas	1. Medical gas center (Automatic Oxygen Manifold; Medical Compressed Air Center; Suction Air Center (Vacuum)) by implementing a backup system to avoid supply failure. 2. 2) SNI/ISO 7396 Medical Gas and Vacuum (2x Oxygen (2 per operating table), Dinitrogen Oxide, Water (Medical Compressed Air), Vacuum, Residual Anesthesia Gas (BSGA); mounted on pendant/ceiling.	100
	Gas and Vacuum Planning	1. Emergency medical gas supply is provided with an installation system. 2. The operating room is equipped with monitoring devices to monitor temperature, humidity, air pressure, and medical gas pressure.	100
	Reliability	Especially for the central operating room, medical gas, oxygen, nitrous oxide, carbon dioxide, medical compressed air, and instrument compressed air are piped to the operating room.	100
	Medical Gas Supply	1. If the operating room is used for laroscope, equip with carbon dioxide.	100

	2. When used for bone surgery, equip with instrument compressed air (UTA) or nitrogren gas-central-pipe sertf. manufacturing-valve area and 3. Alarm-outlet 4. Adjusted flow rate to the needs per room. 5. Equipped with an oxygen flowmeter according to the designation (baby/adult). 6. Equipped with a complete suction/ vacuum regulator set jar adjust the designation of infants or adults per TT. 7. Movable suction unit which is useful for suction/ vacuum regulator equipped with a jar with a capacity of > 3.000 ml. 8. Medical gas and vacuum alarm.	
Wall Outlet	The equipment must function automatically, the outlet will be tightly closed when not in use and open when connected to a medical gas distribution device. The minor operating room consist of: 1. O2 outlet 2. N2O outlet 3. Medical compressed air outlet. 4. Medical vacuum outlet. 5. Anesthesia gas residue outlet (BSGA). Operating room: 1. Each TT in the preparation/ premedication room is equipped with 1 (one) O2 outlet and 1 (one) medical vacuum outlet. 2. The operating room consist of: a. O2 outlet. b. N2O outlet. c. CO2 gas outlet. d. Medical compressed air outlet. e. Instrument compressed air outlet. f. Medical vacuum outlet. g. Anesthesia gas residue outlet (BSGA). 3. Each TT in the recovery room is equipped with 1 (one) O2 outlet and 1 (one) medical vacuum outlet.	100
Planning	Operating rooms that require a high level of room sterility, isolation rooms, and others, are required to regulate: 1. Temperature. 2. Relative air humidity. 3. The air humidity in each room in the Hospital is a maximum of 60%. 4. Cleanliness class. 4. Amount of ventilation air.	100

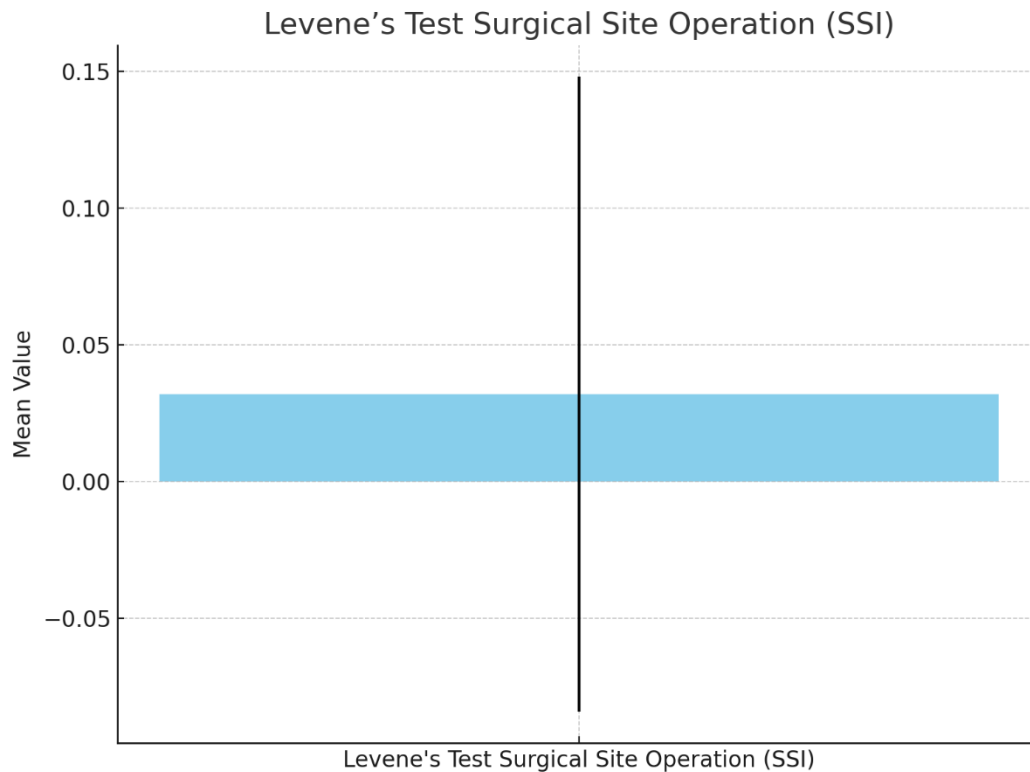
	5. Total air exchange amount. 6. Air pressure. Indoor air pressure can be positive (P), negative (N), or neutral/standard/equal (E) according to the function of the service room. 7. Air distribution in the room. Air distribution is the direction of air flow in the room from the clean area to the dirty area, determined according to the function of the room. A spesial air system is required to avoid disease transmission and obtain thermal comfort levels such as proper temperature and humidity conditions for different disease.	
Technical Requirements	1. The air system in the operating room is individual. 2. Room temperature 21°C + 20°C (occupied) and up to 26°C (unoccupied). 3. Maximum air humidity 60%. 4. Positive room air pressure (min 2.5 Pa). 5. Total ventilation air 4-5 times/hour. 6. Total air exchange 25 – 30 times/hour (occupied) and 8 – 10 times/hour (un-occupied). 7. The room optimizes natural lighting. For artificial lighting light intensity + 3000 lux. 8. If required for action, additional lighting of 1000 lux can be provided. 9. Medical gas and vacuum installation SNI/ISO 7396 (oxygen, vacuum, medical compressed air recommended) – central – pipe sertf. Manufacturing – valve and alarm area – outlet – bed head per TT equipped with adult flowmeter and suction/ vacuum regulator complete with adult per TT. 10. Each bed is provided with at least 5 contact boxes with permanent installation. 11. It is recommended to use monoligtic HEPA laminar ceiling. 12. This room is sterile room with hepa filter (high risk level), room cleanliness ISO 7 (ISO 14664-1 cleanroom standards, 1999). 13. Above the operating table is very sterile area (very high-risk level), cleanliness above the operating table is ISO 6 (ISO 14664-1 cleanroom standars, 199).	100

		14. The operating table is under the flow of sterile air that is evenly distributed at each point from the ceiling (unidirectional air flow) through the hepa filter, with downward movement towards the exhaust inlet (return air) located in the 4 corners of the room made plenum.	
		15. The air velocity out of the monoliglic HEPA ceiling should be 0.15m/sec – 0.3m/sec.	
Capacity		Lighting intensity min 1.000 lux	100
Group		1. The operating room falls into group (yellow zone)	100
		2. Medical locations where there are applied parts intended to be used in applications such as intracardiac procedures, operating/ surgical rooms, and vital care if discontinuity (failure) of supply could cause death.	
		3. Class ≤ 0.5 seconds > 5 seconds ≤ 15 seconds.	
Outlet		1. The operating room electrical system is group, where the electrical power supply must not be interrupted.	100
		2. The electrical system is equipped with an isolation transformer.	
		3. TT preparation is equipped with at least 2 (two) sockets.	
		4. The recovery TT is equipped with at least 4 (four) sockets supplied from at least 2 (two) different fuses/ miniature circuit breakers (MCB).	
		5. The operating room is equipped with a minimum of 2 (two) sockets mounted on pendants. Each outlet is supplied from a different fuse/ miniature circuit breaker (MCB).	
		6. Medical devices that require electrical power greater than 10 (ten) amperes, are provided with special sockets with a separate fuse/ miniature circuit breaker (MCB).	
		7. Corridors are equipped with at least 3 (three) sockets within 10 (ten) meters.	
Health Equipment Standard	Needs Assessment	1. Examination lamp.	76.19
		2. Head lamp.	
		3. Examination table.	
		4. Cystostomy set.	
		5. Drum.	
		6. Korentang.	
		7. Nierbeken.	
		8. Gynecological bed/ obstetric table.	
		9. Delivery instrument set.	

	10. Baby incubator. 11. Infant warmer. 12. Baby scale. 13. Forcep set. 14. Vacuum set. 15. Cardiotocographu (CTG) 16. Doppler. 17. Baby resuscitator. 18. Baby suction pump. 19. Examination lamp. 20. Pediatric patient bed. 21. Pediatric scale. 22. Amputation set. 23. Patient monitor. 24. Operating lamp ceiling type. 25. Operating lamp mobile. 26. Operating table. 27. Oximeter/ pulse oximeter/ oxygen saturation. 28. Portable suction pump/ aspirator/ vacuum. 29. Tensimeter/ sphygmomanometer. 30. Infusion pump. 31. Ventilator. 32. Anesthesia machine. 33. Mayo table. 34. Syringe pump. 35. Gastrocopy. 36. Major surgery instrument set for adult abdomen. 37. Major surgery instrument set for pediatric abdomen. 38. Donut pillow. 39. Blanket warmer. 40. Harmonic scalpel (electrocautery). 41. Laparoscopy set. 42. Minimal invasive surgery set. 43. UV lamp for room sterilization. 44. Palatoplasty set. 45. Holmium laser. 46. Robotic surgery unit. 47. Defibrillator. 48. Anesthesia machine.	
Requirements	When operating a medical device, all procedures related to the operation must be observed. Procedures and steps must be followed sequentially from the start of operation, when the device is attached to the patient until the devices is removed from the patient and the device is returned to its original place.	100
Preparation	Preparation for medical device operation includes checking the completeness of equipment, checking supporting facilities and preparing operational materials.	
Implementation	Implementation of equipment operation needs to pay attention to several aspects.	

	Some aspects that need to be considered include: 1. Applicable services fixed procedure. 2. The relationship between the equipment and the patient. 3. Operation of the tool at the time of the action. 4. Supervision of the function.	
Storage	After the equipment is used, packaging/ furnishing activities are carried out. This activity greatly affects the period of use of the equipment. Packaging/ furnishing activities include: 1. Turning off the equipment according to the procedure. 2. Disconnecting the equipment from the power supply. 3. Cleaning equipment and accessories that have been used. 4. Putting the equipment in place. 5. Recording equipment workload.	100
Decontamination	All equipment to reused, maintained, repaired or destroyed must be decontaminated to ensure that is safe for further handling. The level of decontamination depends on the type of equipment and specific procedures. Decontamination levels include cleaning, cleaning followed by disinfection, and cleaning followed by sterilization.	100
Maintenance	In preventive maintenance is divided into two categories including inspection preventive of maintenance activities that have been carried out.	100
Reporting	In preventive maintenance inspection activities, a checklist is required to record the results of maintenance activities that have been carried out.	100
Testing and Calibration	Provisions regarding testing and calibration of health equipment are carried out in accordance with the provisions of laws and regulations.	100
Average		100

Based on these calculations, the criteria set forth in Minister of Health Regulation No. 40 of 2022 concerning technical requirements for buildings, infrastructure, and medical equipment in hospitals are deemed to be met if: 100% (in accordance with Minister of Health Regulation No. 40 of 2022). Based on the above calculations, the result is 100%, which means that RSU PKU Muhammadiyah Gubug is in compliance with the established standards. Independent samples test for this study shown in Table 3 in this below:

Table 3. Independent Samples Test

Based on Table 3. Independent Sample Test related to surgical site infection, it was found that there was no significant difference between the groups that implemented the Ministry of Health Regulation No. 40 of 2022 and those that had not implemented the Ministry of Health Regulation No. 40 of 2022 in terms of surgical site infection. The t-test for surgical site infection resulted in a value of Sig. = 0.251 (for assumed equal variance), which is greater than 0.05, indicating that the mean difference between the two groups is not significant. While the data from interviews with all informants in this study are obtained in Table 4. as follows:

Table 4. Results of Researcher Interviews with Informants

Date	Question	Informant	Answer
May 05, 2025	Implementation of Ministry of Health Regulation No. 40 of 2022	Head of Administration and General Affairs (informant 1) RSU PKU Muhammadiyah Gubug	RSU PKU Muhammadiyah Gubug - Grobogan has already implemented the regulation. This regulation provides convenience in the development of the Hospital. The regulations also provide safety, comfort, health, and convenience for patients and health workers.
		Person in Charge of Facilities and Infrastructure (informant 2)	This rule provides services and healing to patients as needed due to more complete medical equipment.
		Facilities and Infrastructure Staff (informant 3)	The application of this rule provides convenience in the selection of medical devices and infrastructure needed.
May 06, 2025		Head of Operating Room (informant 4)	Procurement of medical devices in accordance with Ministry of Health Regulation No. 40 of 2022 provides

May 07, 2025		RSU PKU Muhammadiyah Gubug	assistance to services because medical devices are used for patient safety and patient healing.
		Operating Room Attendant (informant 5) RSU PKU Muhammadiyah Gubug	Regulations are socialized to all operating room staff so that maintenance and control of medical devices are easy to use.
		Head of Hospital Facilities and Infrastructure Maintenance Unit (informant 6) RS Aisyiyah Kudus	The implementation of these regulations has not yet been implemented. The regulations still use the C-level Hospital standard.
		Head of Operating Room (informant 7) RS Aisyiyah Kudus	Regulations have been socialized but are not yet needed because the operating room equipment is in accordance with level C Hospital standards.
May 05, 2025	Obstacles in the implementation of Ministry of Health Regulation No. 40 of 2022	Head of Administration and General Affairs (informant 1) RSU PKU Muhammadiyah Gubug	Large costs are an obstacle because they have to rearrange and complete supporting facilities at the Hospital.
		Person in Charge of Facilities and Infrastructure (informant 2)	
May 07, 2025		Head of Hospital Facilities and Infrastructure Maintenance Unit (informant 6) RS Aisyiyah Kudus	Obstacles in planning the implementation of Ministry of Health Regulation No. 40 of 2022 are due to the different technical requirements needed. Other infrastructure already built will be difficult for new development.
		Head of Operating Room (informant 7) RS Aisyiyah Kudus	Implementation of the Ministry of Health Regulation No. 40 of 2022 requires time and effort to conduct training for health workers and hospital administration.
May 05, 2025	Involvement in the implementation of Ministry of Health Regulation No. 40 of 2022	Head of Administration and General Affairs (informant 1) RSU PKU Muhammadiyah Gubug	All hospital management work together so that the budget is allocated according to the needs of the hospital.
		Person in Charge of Facilities and Infrastructure (informant 2) RSU PKU Muhammadiyah Gubug	The infrastructure and medical equipment team makes the implementation of Ministry of Health Regulation No. 40 of 2022 a major task.
May, 07 2025		Head of Hospital Facilities and Infrastructure Maintenance Unit (informant 6) RS Aisyiyah Kudus	If implemented, all facilities and infrastructure teams will be the main task, but other teams also play a role as well as other officers.
May 05, 2025	Control of medical devices in accordance with the	Facilities and Infrastructure Staff (informant 3) RSU PKU Muhammadiyah Gubug	Control is carried out by all medical device users.

May 06, 2025	implementation of Ministry of Health Regulation No. 40 of 2022	Head of Operating Room (informant 4) RSU PKU Muhammadiyah Gubug Operating Room Attendant (informant 5) RSU PKU Muhammadiyah Gubug	
May 05, 2025	Obstacles to the control of medical devices in accordance with the implementation of Ministry of Health Regulation No. 40 of 2022	Facilities and Infrastructure Staff (informant 3) RSU PKU Muhammadiyah Gubug Head of Operating Room (informant 4) RSU PKU Muhammadiyah Gubug Operating Room Attendant (informant 5) RSU PKU Muhammadiyah Gubug	Health workers or new workers who do not have knowledge of Ministry of Health Regulation No. 40 of 2022.
May 06, 2025			
May 07, 2025	Medical Devices according to class C Hospital standards	Head of Operating Room (informant 7) RS Aisyiyah Kudus Operating Room Attendant (informant 8) RS Aisyiyah Kudus	In accordance with Class C Hospital standards.
	Control according to class C hospital standards	Operating Room Attendant (informant 8) RS Aisyiyah Kudus	Control is carried out in accordance with class C standards so that patient services are guaranteed.

Based on the interviews with all informants, RSU PKU Muhammadiyah Gubug has successfully implemented Ministry of Health Regulation No. 40 of 2022, which outlines the technical requirements for hospital buildings, infrastructure, and medical equipment. This implementation is a comprehensive effort that involves both healthcare staff and hospital management. Unlike other hospitals that may limit implementation to specific areas, RSU PKU Muhammadiyah Gubug has extended the application of the regulation to all rooms across the hospital, not just the operating rooms. Before the regulation's implementation, thorough socialization sessions were conducted for all staff members to ensure widespread understanding and compliance. Furthermore, the hospital ensures that medical devices are controlled in line with the regulation, and this responsibility is shared across all departments.

However, challenges persist in fully executing the regulation, particularly concerning the high costs involved. To mitigate this, the hospital has opted for a phased approach, gradually implementing the regulation over time. Another challenge identified is the lack of awareness among new healthcare workers regarding Ministry of Health Regulation No. 40 of 2022. To address this, regular counseling and training sessions are provided to ensure that all new staff members are brought up to speed. The phased implementation, combined with these ongoing training efforts, helps distribute the financial and logistical burden of adhering to the regulation.

On the other hand, RS Aisyiyah Kudus has not yet been able to implement Ministry of Health Regulation No. 40 of 2022. Currently, the hospital operates under the standards applicable to a Type C hospital, which limits its capacity to fully comply with the

regulation's comprehensive requirements. Implementing the regulation requires substantial time, effort, and financial investment, particularly in adjusting infrastructure, medical equipment, and human resources. Although the hospital has made efforts to align its medical equipment, including the operating rooms, with the standards of a Type C hospital, it continues to follow the control measures required for these standards. The hospital staff ensures that medical devices are maintained and managed according to these Type C requirements to provide optimal service to patients.

As indicated in Table X, the implementation of Ministry of Health Regulation No. 40 of 2022 at RSU PKU Muhammadiyah Gubug has resulted in a compliance rate of XX%, covering aspects such as building requirements, infrastructure, and medical equipment. Table Y further demonstrates that 100% of informants confirmed that socialization sessions were conducted across all departments. This data strengthens the findings and underscores the hospital's commitment to adhering to the regulation.

Discussion

This study compares the incidence of surgical wound infections (SWI) in cesarean section patients between two hospitals: RSU PKU Muhammadiyah Gubug, which has fully implemented the Ministry of Health Regulation No. 40 of 2022, and RS Aisyiyah Kudus, which has not yet implemented it. This regulation sets technical requirements related to hospital buildings, infrastructure, and medical equipment aimed at improving infection control and patient safety.

At RSU PKU Muhammadiyah Gubug, no SWI cases were found among 10 patients (0%), while at RS Aisyiyah Kudus, there was 1 infection case among 20 patients (5%). Although this difference appears clinically significant, statistical analysis showed a p-value of 0.251, indicating no statistically significant difference. This lack of significance is likely due to the small sample size and low number of infection events, limiting the statistical power to detect meaningful differences. Nonetheless, these results align with previous literature showing that strict adherence to technical standards in operating rooms can reduce SWI incidence (Fletcher et al., 2021; Surve et al., 2024).

The full compliance demonstrated by RSU PKU Muhammadiyah Gubug with the comprehensive standards—covering hospital building design, infrastructure such as clean water supply and medical gas systems, and strict management of medical equipment—reflects a strong institutional commitment to infection prevention. This thorough compliance is consistent with prior studies emphasizing the critical role of hospital infrastructure and equipment standards in minimizing SWI (Goniewicz et al., 2023; Wahyudi et al., 2023). Moreover, the hospital's ongoing efforts to address structural and minor system issues, improve documentation, and maintain maintenance programs underscore the dynamic and continuous nature of healthcare facility quality improvement (Bhaladhare & Rishipathak, 2025; Endalamaw et al., 2024).

The operating room environment is a complex system where physical infrastructure, environmental controls, and human factors interact to influence infection risk. Proper ventilation, aseptic procedures, and strict traffic flow control are essential to limit microbial contamination, supported by recent evidence highlighting environmental and behavioral impacts on SWI rates (Alruwaili et al., 2023; Nadi et al., 2024). Fundamental design principles such as separating clean and contaminated zones, logical patient flow, and dedicated instrument processing areas are crucial to reducing cross-contamination risk (Sahoo et al., 2024; Schinas et al., 2023). Continuous staff training and adherence to aseptic techniques—including patient skin disinfection and antimicrobial prophylaxis when needed—remain key pillars of SWI prevention (Puro et al., 2022; Tremiterra et al., 1991).

The study also highlights the importance of socialization and training for all hospital staff to build a culture of safety and compliance (Sarabi et al., 2020; et al., 2025). A multidisciplinary approach involving management, healthcare workers, and support personnel aligns with recent research advocating comprehensive infection control programs integrating technical, behavioral, and organizational interventions (Bonaconsa et al., 2024; Buljac-Samardzic et al., 2020). Although medical equipment control and surveillance systems have not been fully implemented, these are recognized as important components in reducing SWI (McLaney et al., 2022; Tandan et al., 2024).

Social and cultural factors also play a significant role in the success of SWI prevention efforts (Braun et al., 2020; Livingston et al., 2022). An organizational culture that promotes open communication, accountability, and teamwork is associated with better compliance with infection control protocols and reduced infection rates (Ahmed et al., 2024; Phelps et al., 2024). Continuous staff training and socialization help embed infection prevention practices into daily routines, so staff who understand the rationale behind protocols tend to comply more, reducing SWI risk (S. Fahnbulleh & Z. Mianue, 2024). Additionally, community trust and patient involvement affect cooperation with pre- and post-operative instructions impacting SWI outcomes (Hickmann et al., 2022; Pokhilenko et al., 2021). Hospital hierarchy dynamics can influence infection control; rigid hierarchies may inhibit junior staff from raising questions or suggestions, while peer influence and respected role models can encourage the adoption of best practices (Ominyi et al., 2025; Paul et al., 2025).

Recent research over the past five years has explored both linear and nonlinear relationships between infection prevention interventions and SWI outcomes. For example, a multi-center study in Southeast Asia found a direct linear correlation between comprehensive staff training programs and decreased SWI rates (Jalaludin et al., 2025; Sun et al., 2024). Other studies similarly showed a linear relationship between implementing technical standards—such as ventilation and sterilization—and reduced SWI incidence (Farré et al., 2022; Totaro et al., 2019). However, other studies revealed more complex dynamics. Khan et al. (2024) observed that infrastructure improvements alone do not always yield proportional SWI reductions without strong organizational culture and staff engagement, indicating nonlinear effects. Dakos et al. (2024) reported that surveillance systems significantly reduce SWI only after reaching certain thresholds of staff participation and training, demonstrating a tipping point phenomenon. Ahmed & Lee (2021) found that the impact of equipment maintenance on SWI rates increased in hospitals with initially high compliance but diminished in facilities with poor infection control (Abalkhail & Alslamah, 2022; Massimino Ucin et al., 2024).

These findings underscore the importance of a holistic and context-sensitive approach to SWI prevention that integrates technical, socio-cultural, and organizational factors. While technical compliance with regulations such as Ministry of Health Regulation No. 40 of 2022 is fundamental, sustained reductions in SWI also depend on fostering a supportive organizational culture, ongoing staff education, and effective communication at all hospital staff levels.

This study has several limitations that should be considered when interpreting the results. First, the small sample size, with only 10 patients from RSUD PKU Muhammadiyah Gubug and 31 patients from RS Aisyiyah Kudus, limits the statistical power to detect significant differences in surgical wound infection rates. The low incidence of infections further reduces the ability to draw strong conclusions about the effectiveness of implementing Ministry of Health Regulation No. 40 of 2022. Second, the cross-sectional and observational design restricts the ability to establish causal relationships between regulation implementation and infection outcomes, as confounding factors such as patient health status, surgical techniques, and postoperative

care were not controlled. Third, the study relies on secondary data from medical records and observation sheets without conducting validity and reliability testing on these instruments, which may affect data accuracy. Fourth, qualitative data from interviews may be subject to response bias and limited generalizability due to the small number of informants. Lastly, the study focuses on short-term outcomes and does not assess long-term effects or patient satisfaction related to infection control measures. These limitations suggest the need for larger, longitudinal, and more controlled studies to better evaluate the impact of the regulation on surgical wound infections. For future research, it is recommended to focus on personalized infection prevention strategies that consider individual patient risks and antimicrobial resistance. Studies should also explore the combined effects of multiple prevention measures, such as improved surgical techniques, antimicrobial use, and postoperative care. Additionally, investigating new technologies and devices for infection control, as well as the impact of staff training and hospital culture, will help understand how to maintain effective infection prevention. Larger, multicenter studies with more participants are needed to better understand how infrastructure, staff behavior, and infection rates are connected, and to find the best ways to reduce surgical wound infections sustainably.

CONCLUSIONS AND SUGGESTIONS

This study demonstrates that full compliance with Ministry of Health Regulation No. 40 of 2022 correlates with lower SSI incidence in cesarean section patients, even though statistical significance was not achieved due to sample limitations.

Theoretical contribution: The findings expand the literature on infection prevention by integrating regulatory compliance frameworks with both clinical outcomes and organizational processes. By applying a mixed-methods approach, the study highlights how technical standards interact with socio-organizational factors such as training, communication, and institutional culture (Creswell & Creswell, 2018; Braun & Clarke, 2006).

Policy contribution: The results provide early empirical evidence supporting the Ministry of Health's regulatory strategy. Policymakers can use these insights to prioritize infrastructure investment, staff training, and phased implementation strategies across hospitals. For administrators, the study underscores the importance of multidisciplinary collaboration and continuous monitoring of compliance to improve patient safety (CDC, 2025).

In summary, while limited in scale, this study offers both theoretical insight and practical guidance. It emphasizes that sustainable reductions in SSI require a multifaceted approach—combining strict regulatory adherence with supportive organizational culture and ongoing education.

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