

# IMPLICATIONS FOR THE QUALITY OF SURGICAL CARE THROUGH THE NON-MAINTENANCE OF HOSPITAL EQUIPMENT

*Implicações na qualidade do atendimento cirúrgico diante da não manutenção dos equipamentos hospitalares*

*Implicaciones para la calidad de la atención quirúrgica por medio del no mantenimiento de los equipos hospitalarios*

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**ABSTRACT: Objective:** To identify the implications of non-maintenance of hospital equipment for the quality of surgical care. **Method:** This is a quantitative, exploratory, descriptive, observational study carried out at a philanthropic hospital in the countryside of Minas Gerais. The technique of direct observation was applied, as well as the evaluation of records related to preventive and corrective maintenance of surgical equipment. **Results:** During the observation period, the equipment presenting most failures during surgical procedures were: electric scalpel, intensifier, and surgical focus. Equipment functionality and maintenance data were compared with manufacturers' recommendations and the scientific literature. **Conclusion:** Failure in surgical equipment maintenance can prolong patients' postoperative recovery, increase morbidity and mortality, and lead to unnecessary financial impact for the institution. It is hoped that the results of this study motivate the multiprofessional team to perform preventive maintenance of equipment before surgeries. **Keywords:** Surgical centers. Surgical equipment. Equipment maintenance.

**RESUMO: Objetivo:** Identificar as implicações da não manutenção dos equipamentos hospitalares na qualidade do atendimento cirúrgico. **Método:** Trata-se de uma pesquisa quantitativa, exploratória, descritiva, observacional, realizada em um hospital filantrópico do interior de Minas Gerais. Aplicou-se a técnica de observação direta e a avaliação de registros de manutenção preventiva e corretiva dos equipamentos cirúrgicos. **Resultados:** Durante o período de observação, verificou-se que os equipamentos que mais apresentaram falhas durante a cirurgia foram: bisturi elétrico, intensificador e foco cirúrgico. Os dados de funcionalidade e manutenção dos equipamentos foram comparados com recomendações do fabricante e com a literatura científica. **Conclusão:** A não manutenção dos equipamentos cirúrgicos pode prolongar a recuperação pós-operatória, aumentar a morbidade e a mortalidade e levar a um impacto financeiro desnecessário para a instituição. Espera-se que os resultados deste estudo possam motivar a equipe multiprofissional à realização da manutenção preventiva dos equipamentos antes das cirurgias. **Palavras-chave:** Centros cirúrgicos. Equipamentos cirúrgicos. Manutenção de equipamento.

**RESUMEN: Objetivo:** Identificar las implicaciones del no mantenimiento de los equipos hospitalarios en la calidad de la atención quirúrgica. **Método:** Se trata de un estudio observacional, descriptivo, exploratorio y cuantitativo realizado en un hospital filantrópico del interior de Minas Gerais. Se aplicó la técnica de observación directa y la evaluación de registros de mantenimiento preventivo y correctivo de los equipos quirúrgicos. **Resultados:** Durante el período de observación, se verificó que los equipos que presentaron el mayor número de fallas durante la cirugía fueron: bisturí eléctrico, intensificador y foco quirúrgico. La funcionalidad del equipo y los datos de mantenimiento se compararon con las recomendaciones del fabricante y la literatura científica. **Conclusión:** La falta de mantenimiento del equipo quirúrgico puede prolongar la recuperación postoperatoria, aumentar la morbilidad y la mortalidad y generar un impacto financiero innecesario para la institución. Se espera que los resultados de este estudio motiven al equipo multiprofesional a realizar el mantenimiento preventivo del equipo antes de las cirugías. **Palabras clave:** Centros quirúrgicos. Equipo quirúrgico. Mantenimiento de equipo.

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## INTRODUCTION

One of the World Health Organization's (WHO) world challenges for surgical patients' safety includes evaluating minimum standards for surgical center (SC) equipment, in addition to the most significant items for patient's safety risk<sup>1,2</sup>. In 2009 and 2014, WHO published guidelines for safe surgeries in order to reduce the occurrence of adverse events and to define safety standards that could be applied to all countries<sup>1,2</sup>.

In this context, some countries in Europe, for example, still cannot improve adverse event rates in hospitals' SC, which confirms that the challenge implemented by WHO is a persistent problem not only in Brazil, but also at a global level<sup>3</sup>.

In Brazil, it is estimated that about 3 to 16% of all hospitalized patients suffer adverse events and more than half of these events can be avoided<sup>4</sup>. The rate of perioperative adverse events is 3%<sup>1</sup>. Besides that, among the surgeries considered to be highly complex, about 16% are performed in hospitalized patients, with significant death rates<sup>5</sup>.

Surveillance of adverse events is one of the gold standard practices that improve patient care during surgeries<sup>2,3</sup>. Evaluation of equipment quality and safety has been critically indicated as a key point for the patient's safe care. Despite the emergent need, few studies have given attention to the importance of this practice, especially in a SCs<sup>3-6</sup>.

A recent study indicates that, according to the International Organization for Standardization (ISO), a laryngoscope, for example, must have the minimum acceptable measure of brightness and luminosity for intubation in case of elective surgeries<sup>6</sup>. In this study, performed at a hospital in Norfolk, Virginia, USA, only 29% of 283 laryngoscopes evaluated matched the standards<sup>6</sup>. However, no adverse events were reported with the use of such equipment.

The SC is one of the most complex units of a hospital; thus, it is more susceptible to adverse events<sup>5</sup> due to surgical interventions and evident transition of different employees. Operating rooms (OR) are structured with equipment that must be functioning properly to ensure patient's safety, reducing the number of recurring incidents in surgical environment.

ORs hold hospital equipment such as scalpels and anesthesia machines, which, despite allowing long maintenance

time interval, must be daily inspected for the simple detection of cable oxidation and gas adjustment, for example. According to the Association Française de Normalization (AFNOR), maintenance is a set of actions that aim at ensuring the proper functioning of equipment, using controls to measure its performance, increase its lifespan and provide safety to patients<sup>7</sup>. Preventive maintenance is essential to extend equipment lifespan, reduce costs and improve safety and performance, but financial resources have been restricting the development of programs for this purpose.

To ensure that the inspection is adequate and done periodically, the institution should have a maintenance schedule, which ensures a minimum level of quality. The frequency of preventive maintenance varies according to the manufacturer's recommendation. When the equipment fails, however, it is necessary to activate corrective maintenance, which consists in repairing the defect that made it stop working.

It is important to highlight that most adversities can be prevented when there is correct management and proper use of equipment by the team. The possibility of an event from occurring during surgery may decrease, but the best way to avoid it is properly planning preventive maintenance.

Bearing in mind the lack of scientific knowledge and the adverse events caused by equipment in SCs, this article looks for a critical discussion about maintenance and adequate conditions of these items. Furthermore, the present work tries to contribute with the improvement of surgical patients' safety, protecting the community from avoidable damages and reducing adverse events in hospitals.

## OBJECTIVE

To identify the implications of non-maintenance of hospital equipment for surgical care quality.

## METHOD

This is a quantitative, exploratory and descriptive study conducted in the surgical center of a philanthropic hospital in the countryside of Minas Gerais, Brazil.

Hospitals provide emergency and hospitalization services. Small, medium and large surgeries are conducted, as well as laboratory and imaging diagnoses. The unit in question performs, on average, 150 to 200 surgeries a month. The technique of equipment direct observation at the surgical center, and the team was trained according to the WHO Observer Manual, made available in Portuguese by The National Health Surveillance Agency (in Portuguese, Agência Nacional de Vigilância Sanitária, ANVISA) and Pan American Health Organization (PAHO)<sup>1,2</sup>. The observation sessions were distributed in morning, afternoon and evening shifts. Observation took 40 to 60 minutes over a period of 7 months, from September 2016 to March 2017.

Data collection was performed by previously trained undergraduate and masters' students. Their training was based on the reading of the following materials: Guidelines for Recalls, Corrections and Removals (Devices) by the Food and Drug Administration (FDA), Second Global Challenge for Patient Safety: Safe Surgery Saves Lives (orientations on safe surgery by WHO), and the reference document for the National Patient Safety Program by the Ministry of Health (MH).

Students were allowed to collect data after achieving at least 85% of agreement with the lead investigator. Students watched surgeries on observation day to check for any adverse events caused by equipment malfunction. The records of preventive and corrective maintenance of the institution's surgical equipment were evaluated.

For observation of surgeries and surgical equipment, a form with the following information related to items' maintenance was used: malfunction, calibration, and occurrence of adverse events due to equipment during surgery. Equipment functionality and deterioration data were compared to manufacturers' recommendations and the scientific literature. Data were analyzed and compared using the Microsoft Excel® program.

## RESULTS

According to data collected during observations, the surgical center has four OR, a post-operative room with three adult beds and one pediatric bed, a wash basin unit with three pedal taps, a room for surgical material storages, and a purge. The operating rooms contain five surgical foci, four of which are fixed on the ceiling and one is portable.

The focus fixed on OR-1 ceiling was not functioning for more than six months. The center also has eight multiparameter monitors, four of which are inside operating rooms and four in the postoperative room.

based on observation sessions, the equipment that presented more failures during surgeries were: focus, intensifier, and electric scalpel. Electric scalpel failed ten times, the enhancer failed seven times, and surgical foci failed three times during surgeries (Figure 1). However, no adverse events were reported due to equipment inadequacy.

Chart 1 shows the equipment assessed and the comparison between maintenance dates, as recommended by both the manufacturer and ANVISA.

## DISCUSSION

In the present study, equipment without maintenance records, as well as an intensifier and an inoperative surgical focus were found in the SC. In hospital practice, surgery delays and cancellations are results of defective intensifiers and the absence of others to replace them. The only intensifier that was working flawed during surgery (Figure 1), and procedures that required this equipment had to be performed at another institution, leading to the necessity of displacing both patients and hospital staff.

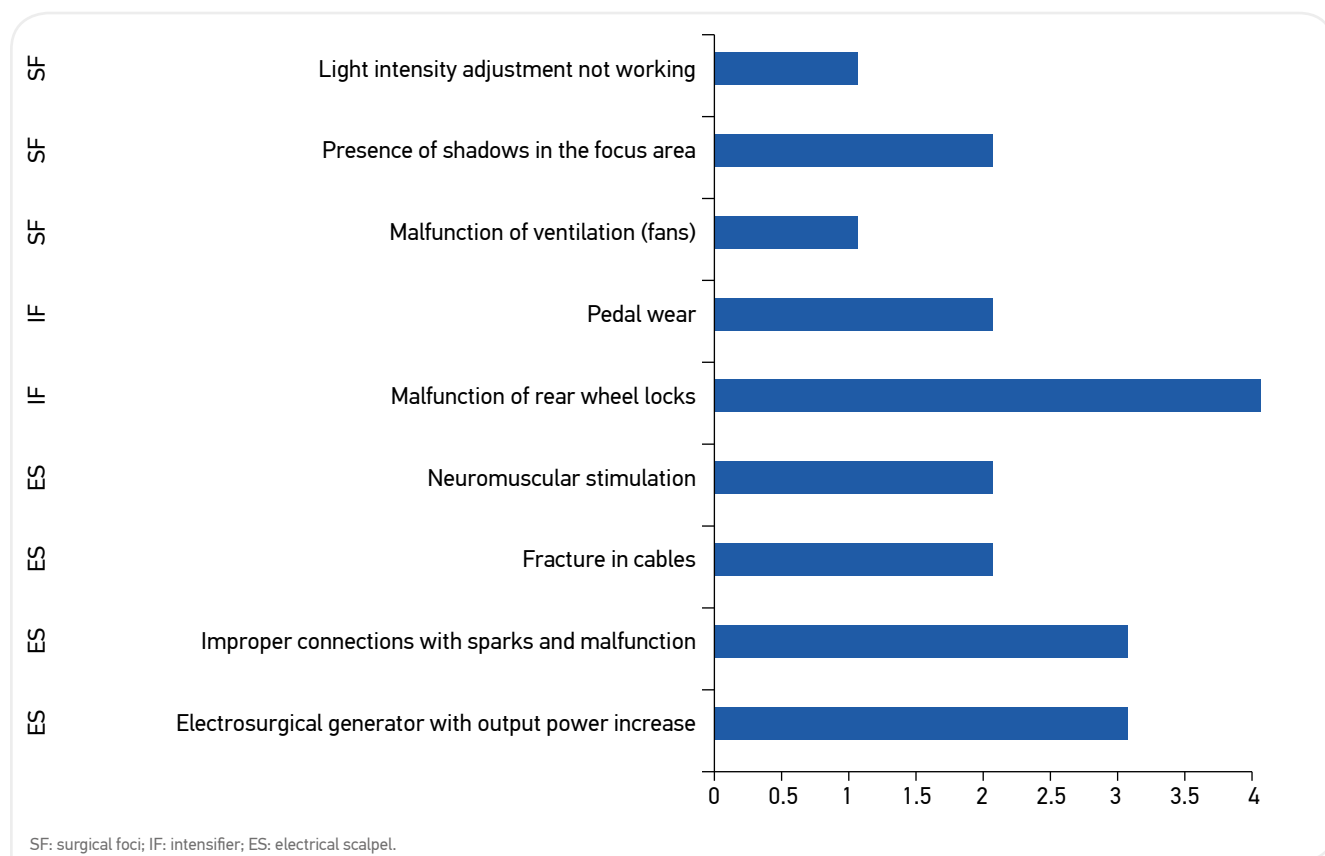
In addition to the manufacturer's recommendation to perform maintenance of intensifiers every six months, simple daily procedures could have avoided these situations, namely, battery performance, ventilation, and electrical performance check, as shown in Chart 1.

The creation of guidelines for Standard Operational Procedures (SOP) is essential to guide maintenance, especially because of manufacturers' recommendations and the fragility of surgical equipment, which can flaw during surgery<sup>6,7</sup>.

Multiprofessional team's awareness is highly necessary so the staff can understand manufacturers' recommendations of equipment use in daily practice, such as cable oxidation check, manometer suitable pressure and lamp operation, thus preventing adverse events from occurring.

The aim of equipment maintenance is to ensure its proper functioning and improve its lifespan, in a way that it is adequate for tasks to be performed<sup>3</sup>.

In the present study, equipment such as electric scalpel, portable aspirator, cardioverter and multiparameter monitors were found to have their maintenance dates overdue.



**Figure 1.** Distribution of failures observed by type of equipment. Diamantina, Minas Gerais, 2017.

**Chart.** Maintenance of hospital equipment, according to the recommendations of the manufacturer and the National Sanitary Surveillance Agency. Diamantina, Minas Gerais, 2017.

Equipment	Specification	Quantity	Last maintenance date	Suggested by the manufacturer and Anvisa
Anesthesia machines	Origami plus k Takaoka®. Asia, Latin America DrägerFabius® Plus, Lübeck, Alemanha	1 3	29/09/2015 No registry date	Preventive maintenance: every 12 months. At each surgery, evaluate: - equipment connections; - exhaust system's operation; - adjustment of gas flow; - aspirator; - hoses; - gas pressure.
Surgical Aspirator	Dia-Pump® Fanem, 089/ R2D2. São Paulo, Brazil	1	18/12/2013	Preventive maintenance: every six months. Every three months: - change the microfilter; - clean the micro ventilator. Check daily: display, circuit board, pressure gauge, pressurizing pump control and hygiene.
Electric scalpel	Wem®, SS-501s. Brussels, European Union Wem®, SS-501s. Brussels, European Union Deltronix®. Ribeirão Preto, São Paulo, Brazil	2 1 1	No registry date 11/12/2015 16/05/2013	Preventive maintenance: at least once a year. Check daily: oxidation in the power cables and physical damage to the equipment housing. Weekly: check power source conditions.

Continue...

**Chart 1.** Continuação.

Equipment	Specification	Quantity	Last maintenance date	Suggested by the manufacturer and Anvisa
Cardioversor	Medtronic Lifepak®20, Tolochenaz, Switzerland	1	21/03/2013	Preventive maintenance: at least once a year. Check daily: Battery charge and discharge applied to a defibrillator analyzer. Every six months: - check DEA; - check defibrillation's standard blades; - check the pacemaker; - check the synchronized cardioversion conditions of the therapy cable.
Surgical Foci	Hanaulux® Blue 80, North Rhine-Westphalia, Germany Hanaulux® Blue 80, North Rhine-Westphalia, Germany Baumer® SA Mogi Mirim, São Paulo, Brazil	1 3 1	No registry date (not working) No registry date 18/07/2013	Preventive maintenance: should not exceed two years. Weekly: - functional and visual inspection of the surgical focus; - check the shelf-life of the carcass; - check the shock absorber of the outbreaks; - check whether the domes are in proper position; - inspect if the lamps are centered and fixed; - check the electrical safety of the lighting system.
Multiparameter monitors	Dixtal Biomédica Ind e Com. Ltda, dx 2023. Manaus, Amazonas, Brazil Dixtal Biomédica Ind. e Com. Ltda, dx 2023. Manaus, Amazonas, Brazil	1 7	30/11/2012 No registry date	Preventive maintenance: yearly. Check: - calibration; - measurement of electrical insulation of the apparatus; - electrical controls, screws and indicators audible and visual. Every three months check: - presence of dry rubbers and connections; - cracking of plastic parts and connectors; - oxidation of metal parts; - cable breakage; - Audible or visual alarm failures.
Intensifiers	OEC Fluorostar 7900. General Electric Company®. Buc, France Opescope Activo Shimadzu Corporation Ltda. Kyoto, Japan	1 1	No registry date (not working) 14/12/2016	Preventive maintenance: every six months. Check: - manual movement of latches and mechanical components; - electromechanical performance; - safety lock performance; - electric performance, - battery operation and electrostatic discharge; - ventilation operation; - operation of image generation and resolution.
Optical Fiber Laryngoscope	M/S SNAA Industries, Paquistan	4	No registry date	Preventive maintenance: before every use. Check: - battery integrity; - correct operation of the lamp; - Damaged items should be replaced whenever necessary.
Surgical Tables	Mercedes IMEC®. São Paulo, Brazil	4	No registry date	Preventive maintenance: at least once a year. Check: - electrical parts; - alignment; - lubrication; - wear; - cleaning.

Anvisa: National Health Surveillance Agency; DEA: Automatic external defibrillator.

This may suggest that hospital managers or the multiprofessional team often wait for a defect to perform corrective maintenance, which can lead to surgery delays, inoperative devices and adverse events in patients, who are often on the operating table.

The Brazilian Technical Standards Association defines maintenance as “the combination of all technical and administrative actions intended to maintain or replace an item in a state in which it can perform a required function”<sup>3</sup>.

A study carried out at a teaching hospital in the South-Center region of the State of São Paulo showed that, among adverse events reported, 31.9% were directly related to surgical equipment<sup>4</sup>.

Another study, carried out at a teaching hospital in the Midwest region of Brazil, reported 42 episodes of adverse events, of which 26.2% were associated with OR structure problems, such as equipment maintenance and materials<sup>5</sup>. Most of these events (73.8%) were caused by problems with the anesthesia machine and burns caused by electric scalpel<sup>5</sup>.

To avoid adverse events, it is necessary to check for oxidation in the electric scalpels’ power cables, physical damage at their casing, and their power source’s condition. This demonstrates how equipment checks prior to surgery can prevent damages to patients who are undergoing surgery. This procedure should be performed by surgeons and technologists, mainly because they wear sterile mitts.

The surgical foci assessed in this study presented shadows, which weakens luminosity upon surgery. A visual inspection should be performed daily, as foci’s minimum requirements must be met so surgeries can be safe.

Three anesthesia devices had no maintenance records. Complications with this equipment are known to be an important cause of death in SCs worldwide<sup>8,9</sup>. This data can be reversed once the multiprofessional team is aware of the importance of daily evaluation.

As for laryngoscopes, daily check is essential so patients in need of tracheal intubation and anesthesia can be safely assisted. The maintenance of laryngoscopes involves, above all, quality and acceptable levels of light. A study carried out in Norfolk (Virginia, USA) assessed 691 laryngoscopes, of which 28% were below recommended standards (between 500 and 867 lux)<sup>6</sup>. In addition, light-measurement tests had never been performed on any of them. Instead, only qualitative visual inspections had been made, which does not guarantee efficiency<sup>6</sup>.

Although visual inspection can identify wear, deterioration and oxidation in equipment, not performing physical and mechanical tests should not be acceptable in healthcare institutions, as these places aim at the best care.

The gas cylinders and supports presented rust all over them, making it difficult to read standard information on it. There was also equipment without seal. Aiming to prevent incidents and adverse events, the institution should create and publish SOPs, routines, guidelines, manuals and other material to standardize techniques, procedures and behaviors.

It is known that more than half of all adverse events caused by surgical equipment can be avoided when maintenance is up to date and when the multiprofessional team itself checks devices before each surgery<sup>6-11</sup>. Although adverse events during surgical interventions are recognized as a public health issue, they are still not acknowledged as such by health institutions<sup>6-11</sup>. Deficiencies in organizational, economic and financial management are the main causes, especially in developing countries.

In 2017, FDA raised questions to a hospital in Michigan (USA), where surgical equipment presented defects during surgeries due to inadequate maintenance, putting the lives of patients at risk<sup>8</sup>. An observational study in England and Wales pointed 6% (n = 754) of patients undergoing surgeries facing adverse events due to the absence of or inadequate maintenance of hospital equipment<sup>8</sup>. The same study found that 12% (n = 116) of patients who had adverse events due to equipment were seriously injured or died<sup>7</sup>. Most health institutions, however, do not disclose quantitative data about these events.

Health institutions should be encouraged to create the habit of recording surgical incidents caused by equipment, which would contribute to the creation of an adverse events’ database. This would demand commitment from hospital management and multiprofessional team on daily vigilance. On the other hand, that would lead to potential safety solutions for surgeries, as recorded and validated data could be used in hospital practice.

The terms “device failure” or “medical equipment” are used by the FDA to regulate and keep track of equipment quality maintenance<sup>8</sup>. Such terms describe the failure of a given material to perform its function, including any deviation or abnormality in its functionality or intended use<sup>10,11</sup>. Therefore, one can understand the importance of producing consistent data aimed at reaching minimum quality requirements and increasing surgical equipment lifespan.

However, despite the challenging proposal of preventive and corrective maintenance, whether for institutional, economic or legal reasons, many hospitals do not dedicate to creating protocols that meet these equipment's minimum quality parameters.

The results of the present study demonstrate the absence of prevention and prolonged time to perform corrective maintenance in hospital equipment. They are only repaired when there are no conditions of use, which then require more time for correction, besides influencing directly on the quality of the assistance provided. The failure to perform experimental tests on defective equipment was a limitation for this study. These tests validate and attest wear and malfunction, especially in electrosurgical generators of electric scalpels, which, therefore, can lead to adverse events such as burns in surgical sites and tissues.

Our findings, however, should motivate the multiprofessional team to perform preventive maintenance of hospital equipment, as well as surveillance prior to surgeries. Finally, inadequate preventive and corrective maintenance of equipment can prolong postoperative recovery, increase morbidity and mortality, besides the financial impact<sup>10,11</sup>. In addition, safety standards and quality care are part of a set of requirements necessary for surgery safety programs in hospitals.

## FINAL CONSIDERATIONS

The present work concludes that the maintenance of hospital equipment is essential, either to provide safe mechanisms for surgical patients or to start a safety program for surgeries aiming at adverse events' prevention.

Due to the complexity of this sector, the surgical center should promote a daily evaluation prior to all surgeries. Equipment should be tested for its status and functionality to avoid incidents during procedures. Thereby, further studies should be carried out to clarify an ideal schedule for corrective and preventive maintenance of surgical equipment.

The lack of records and the bad equipment maintenance in the institution chosen for this study indicate that it is still a challenge for health institutions to adequately keep their devices' maintenance and therefore prevent adverse events with surgical patients. Thus, beyond meeting the objectives of a research that aims to expand and contribute to existing knowledge, fostering social transformations that can lead to reflection, this study proposes quality indicators that enable the implementation and validation of protocols and control.

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