

A risk-based integrated management for patient safety and quality in healthcare services

R. Roque González¹, R.M. Guerra Breña², Y. Chaveco Salabarría³, K.F. Ortiz Jaya⁴, O. Vera Cabezas¹

¹National Center for Minimal Access Surgery Havana, Cuba

²Biomaterials Center, University of Havana, Habana, Cuba

³Center of Medical Biophysics, Santiago de Cuba,

⁴Public Health Fac., High Polytechnic School of Chimborazo, Ecuador

Abstract—Quality of health care services and patient safety has become a matter of interest to healthcare professionals, researchers and governments all over the world. The aim of this paper is to show the implementation of the risk-based integrated management for safety and quality at the National Center for Minimal Access Surgery in Havana, Cuba. Based on the structure, responsibilities and documents established for the health care service quality, thorough studies on patient safety and the risk-based thinking led to the development of an integrated system. This approach shifts the quality and safety management from reactive assessment of complications and incidents to proactive evaluation of the potential risks. Reporting of errors, injuries and complications can play an important role in the continuous health service improvement and as learning opportunities, may avoid future harm to patients.

Keywords— risk management, quality management, patient safety, healthcare services.

I. INTRODUCTION

Errors and injuries are common and often very serious in the delivery of health care. For this reason hospitals have created several offices and committees for managing service quality and patient safety. However, in many healthcare institutions these structures work independently without the understanding that safety is just one of the dimensions of the quality of health care, together with access, timeliness, efficacy, efficiency, appropriate measures and acceptability [1]. In the context of patient safety, errors are defined as a failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning) [2]. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase [3]. To have a valid, reliable, and meaningful error rate an accurate data has to be compiled. However, in the best situations, the rate of reporting or identifying medical errors in the review of the records may not reflect the true rate. In fact, engaging health care professionals and staff about reporting errors, reducing risk and improving the safety and quality is a crucial but difficult task [4].

To manage all dimensions of the health care quality, a risk-based approach may be adopted, focused on identifying the underlying hazards in the health care service that lead to risky situations and finally to errors and injuries [2]. Of course, the appreciation of risks has to be based on the available data about the occurrence and consequences of errors and injuries. Reports about injuries and errors are one of the sources of risk identification. Other potential sources of risk identification include the published literature [5], medical device recalls, consulting experts and patient safety research [6].

The World Alliance for Patient Safety [7] offers a definition of safety risk management for health care services, as activities or measures taken by an individual or a health care organization to prevent, remedy or mitigate the occurrence or reoccurrence of a real or potential patient safety event. Patient safety is the reduction of risk for needless harm associated to healthcare at an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, available resources and the context in which care was delivered weighed against the risk of non-treatment or other treatment.

Considering the drawbacks of having the quality management and patient safety functions in separated structures, the aim of this work is to show the implementation of the risk-based integrated management for patient safety and quality (IMS-SQ) at the National Center for Minimal Access Surgery in Havana, Cuba. The application of the IMS-SQ in biliary lithiasis surgery is demonstrated.

II. MATERIALS AND METHODS

The methodology for the implementation of the risk-based integrated management system for safety and quality includes five stages (Fig. 1) following the Plan-Do-Check-Act cycle. UNE 179003:2013 [8] and ISO 9001:2015 standards are employed as the current normative basis [9].

In the case studied, the organization at first implemented a quality management system and on this basis, an integral system for service quality and patient safety management is developed. In the first stage, “Leadership and commitment”,

the higher echelons identify and assess the risk management to be relevant to a health care organization and makes it known the benefits of the IMS-SQ, decides its implementation and designates the project team.



Fig. 1 Integrated management system implementation project.

In the “Designing Stage”, medical care activities are analyzed identifying and assessing risk through analysis and clinical interpretation. Then the next step is the reduction and elimination of the risk incorporating these activities in the already implemented QMS. For monitoring, review and improvement, the quality management tools are employed.

Data and qualitative information were collected from hospital records and documentation establishes in the QMS.

III. RESULTS

The National Center for Minimal Access Surgery (CNCMA) - a Spanish acronym- is the reference institution in Cuba for minimally invasive medical procedures. In the Center an ISO 9001 quality management systems (QMS) are implemented, consisting of four strategic processes, three key processes and two support processes, as shown in the Fig. 2. The healthcare process includes all the activities (Fig. 3) needed to satisfy the needs and expectations of the patients and their relatives.

In the Evaluation and Improvement process, the QMS incorporates several Committees which look after different aspects of hospital quality and patient safety, such as medical ethics, healthcare service, surgical activities, hospital mortality, prevention and control of infectious diseases, pharmaco-therapeutic practices and transfusion medicine.

Based on the structure, responsibilities and documents established for the health care service quality, thorough studies on patient safety and the risk-based thinking develops an integrated system. The IMS-SQ is based on prevention of risks on each subprocess involved in the medical care.

In general, surgical complications can be divided into preoperative, intraoperative and postoperative. The last two obviously occur while the patients are still in the hospital.

Preoperative risk factors in elective laparoscopic surgery are recognized prior to surgery in order to reduce complications and individualized treatment is implemented as soon as possible. However, some risk factors such as age, previous abdominal surgery and co-morbidities can obviously not be changed before surgery [5]. Regarding the patient’s age, several factors, such as history of hypertension, pulmonary, neurologic and coronary artery diseases, can increase the odds of developing any postoperative adverse events in these patients. Other patient factors, such as obesity, anemia and general nutritional state can be dealt with before surgery.

Preoperative factors also include the adequate identification of the patient, experience of the surgeon and the number of surgical cases involved in the work load. These factors are prevented by means of organizational measures taken as part of the hospital management system.

In the protocols established for each medical procedure, quality indicators are measured including safety issues. Specifically, in the standard operational procedure (SOP) for biliary lithiasis, various process quality indicators are established to assure that the preoperative care adhered to the established protocols.

In the prevention of intraoperative complications, the laparoscopic technique and the medical devices chosen have a great influence and are detailed in the SOP. The anesthetic procedures and surgical preparation are also documented and controlled, including the prevention of acute venous thromboembolism, antibiotic prophylaxis in all surgical patients and sterile procedures while placing central intravenous catheters.

Examples of the safety related indicators in surgery for biliary lithiasis are the following:

- Surgical accidents.
- Injuries of the main biliary system.
- Index of conversion to open surgery.
- Morbidity associated to endoscopic retrograde cholangiopancreatography with endoscopic sphincterotomy (ERPC-ES).
- Mortality associated to ERPC-ES.

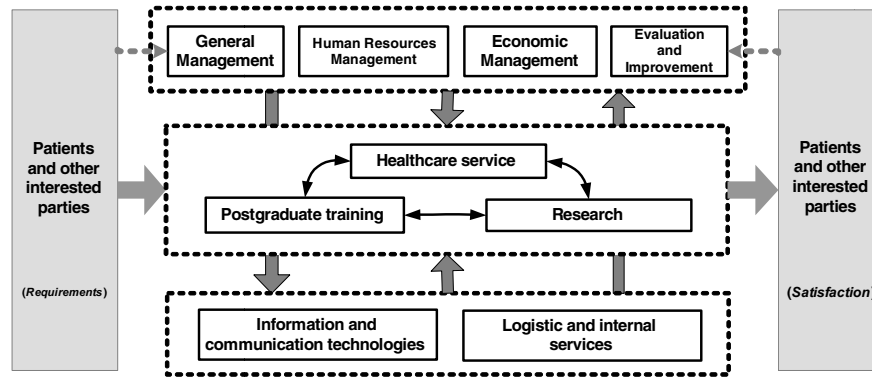


Fig. 2 Process map of the quality management system of the National Center for Minimal Access Surgery.

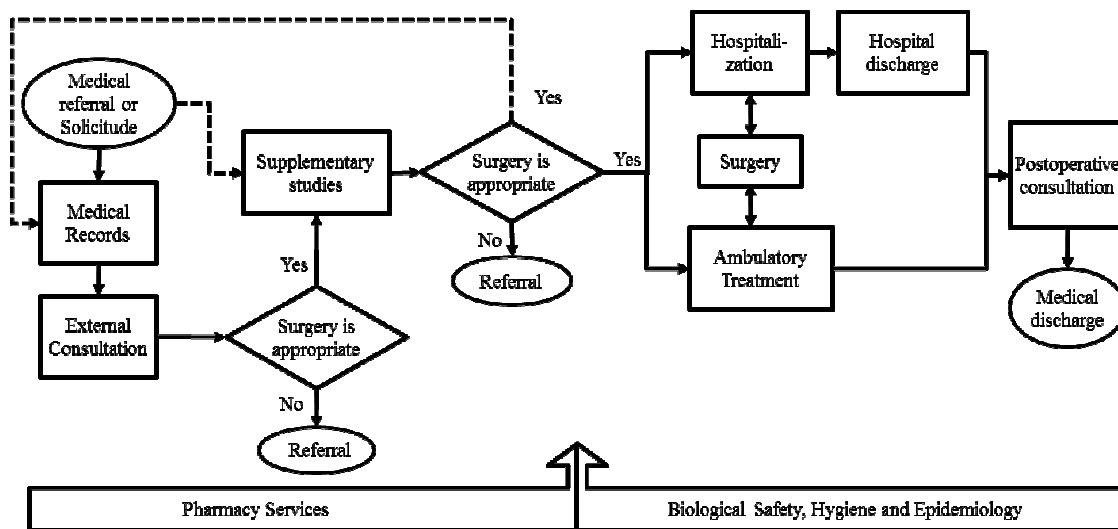


Fig. 3 Process diagram of the healthcare service in the National Center for Minimal Access Surgery.

A set of potential in-hospital postoperative complications that might represent patient safety events are identified, such as, adverse drug events, surgical site infection, central venous line infection, and ventilator-associated pneumonia. Other nosocomial infections may result from lack of proper hand hygiene.

Adverse events in the SOP are recorded. Several indicators in the post-surgical period at the Intensive Care Unit are established, such as:

- Complications in ventilated patients.
- Morbidity in ventilated patients.
- Mortality in ventilated patients.
- Morbidity associated to sepsis.
- Mortality associated to sepsis.

The safety outcomes are discussed in the corresponding Service and the Hospital Quality Committees, based on the detailed description of the events in the patient's clinical

record. Of course the first thing to do when a complication occurs is to respond adequately in order to minimize its effect on the patient, and then record what happened and/or what was done. The causes of the errors or injuries are analyzed and the corrective measures are taken. The purpose of these analysis are not only to know what happened and how, but also to utilize the incident to identify the faults of the medical care process. The discussion and measures taken are important feedback for the IMS-SQ improvement.

Registration, imaging, clinical laboratory and blood bank are very important subprocesses to assure the quality of the health care service and patient safety, in order to guarantee the proper inputs for the surgical act and the postsurgical monitoring. Also the patient flow to the operative theater and back to the hospitalization room is accompanied by nursery personnel to prevent accidental falls and to ensure the correct identification of the patient. The recount of in-

struments, gauzes, needles, etc. by the nurse is obligatory after each intervention before the patients leave the surgery room. All these activities are recorded and are strictly supervised.

In the CNCMA, not only the medical care process is involved in the risk management of patient safety, but also the research and postgraduate training process develops projects to predict morbidity and mortality of various surgeries, including for biliary lithiasis surgery, based on the predictive risk factors. Support processes related to maintenance and metrological assurance of medical devices, hospital cleaning and the diet are also involved in patient safety.

The survey of patient satisfaction includes safety issues and allows the perception of patients and their relatives about the medical service provided. Every patient complaint is informed to the corresponding service. Those related to satisfy the medical needs and comfort of patients and their relatives are analyzed by the board of directors and due action is taken.

Indicators reported in 2015 show a hospital mortality of 0.6%, a rate of infection of all surgical wounds of 0.9% and an urgent reoperations ratio of 0.5%. These quality outcomes are a result of the work done by all staff at the hospital in the framework of the risk-based integrated management for patient safety and quality.

IV. DISCUSSION

Laparoscopic cholecystectomy remains the treatment of choice for symptomatic cholelithiasis, partially because of the shorter recovery period, decreased postoperative discomfort, improved cosmetic results and fewer complications compared to open surgery. However, approximately 5% of laparoscopic cases are converted to an open procedure secondary to difficulty in visualizing the anatomy or a complication. Even so, the risk management is necessary to improve the quality of the provided medical care, which includes the patient safety. Complications such as infection, bleeding, bile leakage, injury to the bile duct, injury to the intestine, bowel and blood vessels, deep vein thrombosis, risks of the general anaesthesia and the appearance of the post-cholecystectomy syndrome are recorded. International data suggest that the rate of trocar related complications is less than 3% [10].

A risk-based approach shifts the quality and safety management from response to the assessment of complications and incidents to proactive evaluation of the potential risks. This approach has the added value of involving frontline staff in this process [11], and also its positive connotation, due to the recording of measures taken to reduce or eliminate risks which results in enhanced safety. Health care staff

is encouraged to actively seek out potential risks, even though they might not have led yet to an error or injury. The risks are then communicated and eliminated whenever possible. The accurate identification and recording of errors, injuries and complications can reflect an institution's patient safety and quality record, and also they play an important role in continuous health service improvement because identified errors are learning opportunities that allow prevention of future harm to patients.

V. CONCLUSIONS

The integrated management system for safety and quality results in better performance of the National Center for Minimal Access Surgery and more efficient use of organizational resources, based on risk management approach.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

REFERENCES

1. Runciman WB, Williamson JAH, Deakin A, et al. An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification. *QualSaf Health Care*, 2006, 15:i82-i90.
2. Scanlon MC, Karsh B-T, Saran KA. Risk-Based Patient Safety Metrics. In: Henriksen K, et al. editors. *Advances in Patient Safety: New Directions and Alternative Approaches Vol. 1* Rockville (MD): Agency for Healthcare Research and Quality; 2008 Aug.
3. Dücker et al. *Safety and risk management in hospitals*. The Health Foundation, London, 2009.
4. Leviton J, Valentine J. *How Risk Management and Patient Safety Intersect: Strategies to Help Make It Happen* March 24, 2015.
5. Kirchoff P, Clavien P-A, Hahnloser D. Complications in colorectal surgery: risk factors and preventive strategies. *Patient SafSurg* 2010, 4:5.
6. Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. *QualSaf Health Care*, 2003; 12: 2-7.
7. WHO, World Alliance for Patient Safety 2009.
8. UNE 179003:2013 *Servicios sanitarios. Gestión de riesgos para la seguridad del paciente*. AENOR, Madrid; 2013.
9. ISO 9001:2015. *Sistemas de gestión de la calidad. Requisitos*. Organización internacional de Normalización, Ginebra; 2015.
10. Fuller J, Scott W, Ashar B, et al. *Laparoscopic trocar injuries*. A report from U.S. Food and Drug Administration, Nov. 7, 2003
11. Morag I, Gopher D. A reporting system of difficulties and hazards in hospital wards as a guide for improving human factors and safety. Paper presented at the Human Factors and Ergonomics Annual Meeting. San Francisco, CA; 2006.

Author: Rosa Mayelín Guerra Breña
 Institute: Biomaterials Center, University of Havana
 Street: Ave Universidad
 City: Havana
 Country: Cuba
 Email: mayelin@biomat.uh.cu