Patient Safety and Surgery: the Experience of the Lombardy Region. A Project on External Evaluation of Best Practices Implementation

Luciana Bevilacqua¹; Giulia Domeniconi²; Chiara Picchetti¹, Davide Mozzanica¹, Elisabetta Brivio¹, Luca Merlino¹, Liviana Scotti¹, Romina Colciago¹, Enrico Comberti¹, Anna D'Andrea¹, Paola Garancini¹, Maristella Moscheni¹, Chiara Oggioni¹, Cristina Oppezzo¹, Paolo Trucco¹, Antonio Vitello¹, Simona Amato¹, Enrico Burato¹

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Abstract

Meta-analysis studies published over the past 20 years document that approximately 10 -14 % of hospitalised patients have an adverse event in Surgery and at least half of these adverse events are considered preventable using the current standards of care.

In order to improve the safety of surgical patients and increasing adherence to current standard of care in surgery, including communication within the team and teamwork, in 2007 the WHO launched the campaign "Safe Surgery Saves Lives". The WHO has also built a checklist for safety in the operating room containing 19 item in support of the operating team. The Ministry of Health in 2009 has taken the instruments produced by WHO in the "Guide to Safety in the operating room: Recommendations and Checklist".

Studies conducted in industrialized countries report a strong heterogeneity in compliance to the *check list* for the surgical safety, with a range of between 38% and 96%.

The aim of this project was to adopt the methodology of the external "peer review" to improve quality and patient safety applied to the surgical process and assess the degree of implementation of good practice in the operating room, both in public and private structures.

Between 2015 and 2018 we have carried out 16 external evaluation visits. These visits included a first plenary session followed by the inspection of the operating theaters identified and a second plenary session. Several factors emerged during the visits; these factors represent both the strengths and criticalities of the organizations.

The creation of a team of experts, coordinated by the Lombardy Region with the role of leadership, using the "peer review" methodology, is the leverage to promote among operators the growth of awareness of the usefulness of the tools.

Background

Meta-analysis studies published over the past 20 years document that approximately 10 -14 % of hospitalised patients have an adverse event in Surgery and at least half of these

¹Working group of Lombardia Region

² Medical Resident

adverse events are considered preventable using the current standards of care^{1,2,3}.

Surgery is a central element in health care with an estimated 234 million surgical procedures performed each year worldwide⁴.

Studies from industrialized countries indicate that permanent disability or mortality rates range between 0.4% to 0.8% of all surgical procedures. Complications are common and occur in 3% to 16% of all surgical procedures 5,6. In summary, this suggests that a minimum of at least 1 million patients die after surgery and 7 million patients are injured by surgical complications annually⁴.

Several studies report that approximately 50% of surgical adverse events can be considered preventable⁷ and, according to an estimate made by the WHO, every year half a million deaths related to surgery could be prevented^{4,8}.

The incidence of surgery-related adverse events combined with the increasing volume of surgery, the mortality rate and the avoidance of the same, result in an important healthcare problem in the world9.

In Italy, the volumes of surgical activities represent 40.6% of all acute hospital admissions. During 2007 about 4 million 600 thousand patients were discharged after interventions or surgical procedures. Almost 3 million of these surgical procedures were performed in the ordinary regime and just over a million and 600 thousand in day-surgery¹⁰.

Several epidemiological studies have been conducted at the national level on the incidence of surgical site infection^{11,12,13,14,15} but to date there are no data about the incidence of adverse events associated with surgical care¹⁶.

Methods

In the Lombardy Region, according to an analysis conducted between 2010 and 2012, 40% of the adverse events occurring in surgery/ are related to surgical procedures ¹⁷.

Despite advances in medical technology and surgical techniques, there is an ongoing need to optimize the quality of surgical care and patient safety¹⁸.

According to WHO, reducing the risk of surgery goes through the pursuit of specific objectives: the correct identification of the patient and the surgical site; the prevention of risks associated with anesthesia, cardiopulmonary complications, blood loss, allergies and adverse drug reactions. It is also important to prevent infections of the surgical site and the retention of gauze and surgical instruments, ensuring traceability of materials, ensuring the reporting of critical events and monitoring the surgical process through the measurement of surgical capacity, volume of activity and results¹⁷.

Epidemiological data show that most of the errors in surgery are not caused by technical problems but a failure of teamwork skills, leadership, communication, decision-making and situational awareness^{19,20}. The Joint Commission on Accreditation of Healthcare Organizations 2004 National Patient Safety Goals focused on the problem of surgical errors and advocated "active involvement and effective communication among all members of the surgical team" as an essential component of patient safety in the operating room ^{21,22}.

In order to improve the safety of surgical patients and increase adherence to current standard of care in surgery, including communication within the team and team work, in

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2007 the WHO launched the campaign "Safe Surgery Saves Lives" and in 2008 published a series of recommendations for safety in the operating room that aim to improve the safety of surgical procedures through the definition and promotion of recommendations and safety standards that can be adapted in different countries and operational setting, strengthening the pre-operative, intra-operative and post-operative processes.

The WHO has also built a checklist for safety in the operating room containing 19 items²³ in support of the operating team, with the aim to improve adherence to the implementation of safety standards recommended for the prevention of avoidable adverse events.

The WHO surgical checklist is used in >4,000 hospitals ²⁴.

In 2009 the Ministry of Health adopted the instruments produced by WHO in the "Guide to Safety in the operating room: Recommendations and Checklist".

The checklist consists of three parts:

- 1. **Sign in**: checks before surgery
- 2. **Time out**: checks to be performed after induction of anesthesia and before surgical incision
- 3. **Sign Out**: controls during or immediately after the closing of the surgical wound and before the patient abandons the operating room.

Studies on the application of these instruments scientifically show a substantial decrease in rates of adverse outcomes in surgical patients. Specifically, the implementation of safety *checklist* in the operating room is associated with a reduction in the mortality rate^{25,26,27,28} and post-operative complications^{7,9,25,29,30,31,32,33,34}.

Studies conducted in industrialized countries report a strong heterogeneity in compliance to the *checklist* for the surgical safety, with a range of between 38% and 96%^{35,36,37,38,39}.

The full acceptance of medical innovations, regardless of their significance, generally takes several years⁴⁰. This process takes even longer when multiple medical disciplines are involved.

The introduction of the surgical *checklist* is a major change in any surgical setting and numerous barriers to the effective implementation of this tool have been identified.

It has been shown that a poor implementation strategy is an important organizational barrier to effective uptake of the *checklist*⁴¹.

It is possible that the checklist is seen as just a "rite of passage" and provide a false sense of security within the surgical team, but no real improvement for patient safety⁴².

This project is carried out within the activities of Risk Management provided in the Lombardy Region between 2015 and 2018. The aim of this project is to adopt the methodology of the external "peer review" to improve quality and patient safety applied to the surgical process and then assess the degree of implementation of good practice in the operating room, both in public and private structures.

The "peer review" is a no inspection methodology whose purpose is to share experiences about implementation of the tools for the safety of patients in surgery and about a possible dissemination and transferability of these experiences in order to have a progressive improvement of the system.

The specific objectives of this project are:

- Knowing the level of dissemination of culture for patient safety in the Lombard health companies
- The exploitation and peer comparison on experiences related to the implementation of good practices in the Companies (public and private), with specific focus on the checklist for safety in the operating room, by referring to the "Manual for Safety in the Operating Room: recommendations and checklists"
- The transfer of good practices in other contexts
- The verification of the consistency of a measurement system on the implementation of the tools
- The creation of a multidisciplinary team of "peer reviewers".

Among the systems of external evaluation it was decided to have as a base the professional accreditation, or "peer review". It is a process of evaluation of professional performance by one or more persons operating in the same field and with the same level of qualification and it is characterized by the "parity" between evaluators and evaluated, understood in a professional sense (the same discipline, the same level)⁴³.

Applying this methodology, we introduce some basic concepts:

- The activity will include voluntary participation
- The scope and the evaluation methods are known and shared
- The external "peer review" is one of the health activities valuation technique aimed at verifying and improving the quality and, in particular, the safety of patients
- This is a comparison of equals in which all members of the Board of Visit and the subjects evaluated have equal professional dignity regardless of the role and job title
- The activity of the external evaluation of the Lombardy Region project focused on the development and peer comparison on the implementation experience of the surgical checklist
- The activities subject to external evaluation must be based, where available, on scientific evidence
- Central elements of the external evaluation are the correct approach and the presence of results
- The results should be objectified, where possible, using result indicators (Ex.: reduction in the number of adverse events object of experience) or at least process indicators (Ex.: number of patients undergoing the identification procedure of the surgical side etc.)
- In a perspective of systemic approach to evaluation this methodology has multiprofessional and multi-disciplinary features
- External evaluation is coordinated by the Lombardy Region in collaboration with scientific societies and/or reference professional associations (and/or well-known experts).

The external evaluation process is represented in Figure 1 "The path of external evaluation - Peer Review: flow - chart".

The path begins with the definition of the object of the assessment: strategies for implementing the *checklist* for surgical safety within the Lombard, public and private accredited structures.

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The program provides a first self-assessment phase, carried out through a self-assessment grid, aimed at detecting the degree of implementation of the Ministerial Recommendations for the prevention of sentinel events in the surgical field.

This questionnaire is filled in by the structures involved in the visit and sent, prior to the external evaluation, to the visiting board, together with the program containing the details of the day (date, duration ...).

The results of the self-assessments will be discussed and verified during the visits, through the analysis of the documentation provided and the direct observation of the surgical activities.

Subsequently, as part of the preparatory activities of the external evaluation visit, the Multi-Professional and Multidisciplinary Board of Visits is set up. The Evaluation Team consists of six to seven external components (representatives of the Region, surgeons, professional nurses, risk managers, engineers, representatives of scientific societies and / or professional associations of reference, possible observers) and internal components identified in the structure of the external evaluation visit (hospital management, risk manager, surgeons, nursing coordinators, professional nurses...).

Evaluation visits have a total duration of 5 - 6 hours and include a first plenary session, lasting 30 minutes - 1 hour, followed by an inspection at the operating rooms identified and by a second plenary session, of equal duration of about 1 hour.

During the first plenary session the company subject to the external evaluation discusses with the Board of Visits the modalities with which, within the structure, the Ministerial Recommendations have been implemented.

Subsequently the Visiting Board carries out an inspection inside the operating rooms; the project involves the observation of preoperative, intraoperative and postoperative activities. The settings subject to inspections are established with discretionary criteria by the companies involved in the external visit.

During the inspections, the Evaluation Team evaluates the structural and organizational aspects, the documental aspects, analyzes the surgical patient's pathways, conducts interviews with the operators and, sometimes, with the operands.

During the second plenary session we discuss the strengths, weaknesses or criticalities and opportunities for improvement in surgical safety identified by the Evaluation Group and reported on a final report prepared according to a predefined format.

In the event that the external evaluation visit through peer review has a positive outcome in terms of dissemination of good practices, the possibility of transferring the activities highlighted in other Lombard healthcare areas is evaluated.

In the event that the assessment visit should have a negative outcome, the Evaluation Group suggests improvement interventions. The external evaluation program provides for the possibility of a possible second external visit, following the implementation of the suggested actions.

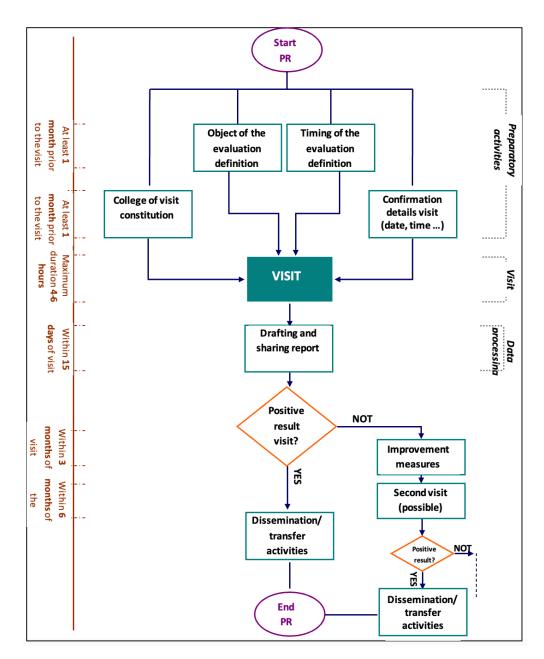


Figure 1. The path of external evaluation - Peer Review: flow - chart

Results

Using the methodology described 16 visits of external evaluation were conducted.

During the first plenary session, the companies audited presented to the Visiting Board their surgical activity data and their own set of operating blocks and related surgical rooms.

Subsequently, were analyzed the ways in which, within the structure, the Ministerial Recommendations were implemented. The processes that led to the drafting of the surgical safety *checklist* within the individual companies in Lombardy were analyzed in detail. Each reality subject to external evaluation has adapted the checklist to the

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characteristics of its local surgical organization and has integrated the use of the tool within the processes already existing in its operating context.

During the evaluation visits, the regional group discussed the difficulties encountered in the implementation of the *checklist* and related solutions, with particular regard to some resistance to change by health personnel.

The corporate procedures, including the documentation relating to the informed consent to the surgical intervention and to the perioperative antibiotic prophylaxis, were subsequently illustrated to the Evaluation Group.

The companies audited presented their data on adverse events and sentinel events to the Board of Visits. In addition, the internal Clinical Risk Management and Incident Reporting systems were presented, along with their specific characteristics.

The initial briefing was followed by an inspection at the operating blocks. Surgical areas audited were chosen at the discretion of each Company. Generally the visits affected areas of excellence and critical areas of each reality. The field tests have affected operating theaters where major surgery is performed but also areas with day/week surgery activity, outpatient surgeries, delivery rooms, recovery rooms.

The site investigations at the operating theaters have been very interesting and useful for the understanding of the dynamics of the implementation and use of check-list for surgical safety.

During the inspections, the audit team evaluated structural and organizational aspects, observed the behavior of health workers and the relative dress code, and examined documental aspects (for example, the checklist for the surgical safety of operands and the informed consent to the intervention), analyzed the pathways of the surgical patient (starting from the time of pre - admission) and conducted interviews, both with the various professionals involved and with the operands. Preoperative activities were observed, such as patient identification and surgical site marking, intraoperative activities, such as Time Out, and postoperative activities, such as postoperative care management.

The surveys carried out so far have taken place in a climate of participation and sharing by the staff of the Company audited.

It showed the willingness of the structures to fully understand the internal failure to their system for safety in surgery in order to implement actions for continuous improvement.

The second plenary session has always been attended by Hospital Management in order to directly take note of the strengths, the weaknesses and opportunities for improvement in surgery for security suggested by the team audit.

During the visits emerged numerous strengths and weaknesses related to the implementation of the checklist.

First of all, within all the facilities visited, it emerged that the implementation of the use of the checklist for surgical safety was supported by a strong commitment by the hospital management and was characterized by a deep and widespread involvement of all operators.

Essential is that, in line with what is reported in the international literature^{42,44}, the path of introduction and implementation of the checklist is strongly supported by the top management companies that should consider this change as an organizational priority and should provide constant support to the whole process. The hospital management, in

order to increase the adhesion to the instrument, should assume an attitude of authority, not of authoritarianism ⁴⁵.

Moreover, within the majority (75%) of the companies audited was found an in-depth knowledge on "patient safety".

Numerous scientific evidence show that a climate of collaboration within the team surgery is essential for the success of surgery and to prevent the occurrence of perioperative accidents ^{31,39,46-48}.

From a structural point of view within the private Lombardy realities have been observed operating theaters characterized by a logistics and a technology of excellent quality. In these companies, the presence of logical and well-ordered processes emerged, illustrated by algorithms and flow charts. Within the public structures have been observed numerous limits of structural adequacy, the need for restructuring and problems related to the reconditioning and environmental sanitation systems.

During the visits was noted a lack regarding the sanitary aspects within almost all (75%) of the observed realities. Specifically, non-strict observance of dress code by operators was observed (use of jewelry and mobile phones). Some facilities were lacking of the hydroalcoholic gel for hand hygiene sometimes a poor hand-washing technique was observed.

The Evaluation Team underlined the fundamental importance of structural, logistic and cleaning adequacy and stressed the importance of improvement environmental reconditioning systems and surgical instruments sterilization processes ⁴⁹.

The surgical checklist is, in most of the structures involved in the self-assessment visit, a paper tool. Just in a few (fives) companies was computerized. Within few realities, even the operative report is a paper tool. The form for the gauze or other material, generally paper-based and included in the checklist, was only computerized within five companies audited.

The Evaluation Team highlighted how the lack of informatization could be an obstacle to the work of the operators. However, where the checklist has been computerized some criticalities in its use have been highlighted. It is necessary that the information systems in use, to support the operators, have a functionality and continuity that does not compromise the efficiency of the organization of the operating rooms.

A central topic emerged during the assessment visits, was the traceability of all the operators involved in the surgical *checklist*. Only in five evaluated companies, on the checklist is requested the application of the triple signature by the surgeon, anesthesiologist and the operating room nurse. Within the other facilities involved in the visit, no signature is required on the surgical safety checklist or only the signature of the nurse is required. In some Lombardy companies, even on the sheet relating to the gauze count or other material, only the signature of the nursing staff is required.

The entire Evaluation Group agreed on the need for the presence of the signature of all the operators involved in the process as formal assumption of responsibility. It is not possible to govern and trace a process without understanding who governs it and traces it. In fact, the regional group underlined how the surgical setting is a setting that involves the entire team, with different professional figures, each one involved and responsible according to their own competence.

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Only within four facilities visited, the use of the operating room safety checklist and of the surgical material count sheet has been implemented within all surgical settings, not just inside the theatre where major surgery is carried out but also in settings where surgical procedures are performed with low complexity and interventional maneuvers.

Within a few particularly virtuous realities, "customerized" checklists have been elaborated in specific areas, for ex. in outpatient ophthalmic surgery, in hemodynamics, in electrophysiology-stimulation, in interventional radiology, in endoscopy.

The Evaluation Team highlighted that numerous adverse events occur in low complexity settings. The implementation of the checklist should be extended even in settings where are performed "minor" surgical procedures.

In fact, it has been shown that the concentration of professionals is greater during interventions with a high and intermediate complexity, while it is lower during interventions with less difficulty⁵⁰.

Finally, according to a survey conducted on more than one thousand orthopedic surgeons specialized in hand surgery, 21% of the interviewed doctors declared that they had committed, at least once during their career, an incorrect identification of the surgical site⁵¹.

Within the other realities visited, the check-out barrier is unclear: the staff involved in the visited operating blocks provided heterogeneous answers about what happens if there is a checklist not filled in the required items (see case of limb unmarked).

From the inspections it has also emerged that the "blocking" value of the checklist for safety in surgery is only real within the most virtuous reality. The non-compliance with the elements required by the operating room checklist generally determined only the postponement of the surgical intervention; only in isolated cases has led to the blocking of the activity and, therefore, to the non-execution of the planned surgical intervention. Unfortunately, there is no activity of reporting or monitoring of such events, if not within a single company.

Furthermore, within the majority of the structures involved in the external evaluation visit, non-conformities related to the use of the checklist for safety in surgery were observed.

The Evaluation Team noticed situations where the checklist was adequately completed in relation to the presence of the informed consent to surgery but the same was absent in the medical record. The regional group has, in some circumstances, noted the lack of context between the compilation of the checklist and the execution of the verification actions. Sometimes, in the presence of the Evaluation Team, the Time Out was not performed before the surgical intervention was performed.

In order to be a real improvement for patient safety, the checklist must be an operational tool and its compilation should not be considered a simple bureaucratic procedure. Documenting the compilation of an instrument is not the same as adopting a behavior.

Only within some Lombard realities (50%) there is a systematic check of the application of the surgical checklist and of the adhesion to the procedure for the prevention of the retention of gauze, instruments or other material within the surgical site. It has been shown that the assessment of compliance with the methodologically correct use of the checklist for safety in surgery has the same importance as the evaluation of outcomes^{52,53}.

Conclusion

Numerous initiatives have been proposed during the years at regional and local level to support the implementation of the instruments for the safety of patients in surgery and there are many critical issues related to incorrect use of the instruments themselves.

The creation of a team of experts, coordinated by the Lombardy Region with the role of leadership, using the "peer review" methodology, is the leverage to promote among operators the growth of awareness of the usefulness of the surgical checklist.

It is not enough to introduce the *checklist* and to define a training program but it is instead essential to monitor the real application of the instrument with appropriate indicators over the years and gradually introducing interventions step by step to "shaping" the team behavior and make it adherent to the checklist requirements.

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