

PDCA CYCLE FOR PREPARING A SURGICAL SAFETY CHECKLIST*

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ABSTRACT: The aim of this study was to use the continuous quality improvement methodology in preparing a surgical safety checklist for the pre- and postoperative periods in inpatient units. The research was carried out with 16 nurses participating from 8 surgical units at a university hospital in south Brazil between March 2013 and October 2014. The joint elaboration of the checklist was guided by the continuous improvement cycle and by the Safe Surgery Saves Lives program. The checklist was subjected to a pilot test with 450 instruments filled out and analyzed by descriptive statistics. After adjustments made from the evaluation, it was approved with the title "Pre- and Postoperative Surgical Safety Checklist" with 85 indicators grouped into 6 categories: I) Identification, II) Pre-operative, III) Immediate Postoperative, IV) Mediate Postoperative, V) Complications, and VI) Hospital Discharge/transfer. The instrument can contribute to preventive actions of errors, monitor signs and symptoms, and produce indicators for safe assistance for the surgical patient.

DESCRIPTORS: Checklist; Pre-operative care; Postoperative Care; Patient safety.

CICLO PDCA PARA ELABORAÇÃO DE CHECKLIST DE SEGURANÇA CIRÚRGICA*

RESUMO: O estudo objetivou utilizar metodologia de melhoria contínua da qualidade na elaboração de *checklist* de segurança cirúrgica para os períodos pré e pós-operatório em unidades de internação. Realizou-se pesquisa participante com 16 enfermeiras, em oito unidades cirúrgicas de um hospital universitário do sul do Brasil, entre março de 2013 e outubro de 2014. A elaboração conjunta do *checklist* foi norteadada pelo ciclo de melhoria contínua e Programa Cirurgias Seguras Salvam Vidas. O *checklist* foi submetido a teste piloto com 450 instrumentos preenchidos e analisados por estatística descritiva. Após ajustes decorrentes da avaliação, foi aprovado com o título "Checklist de Segurança Cirúrgica Pré e Pós-operatório", com 85 indicadores agrupados em seis categorias: I) Identificação, II) Pré-operatório, III) Pós-operatório Imediato, IV) Pós-Operatório Mediato, V) Complicações e VI) Alta Hospitalar/transferência. O instrumento pode contribuir para ações preventivas de erros, monitorar sinais e sintomas e produzir indicadores para assistência segura ao paciente cirúrgico.

DESCRIPTORIOS: Lista de checagem; Cuidados pré-operatórios; Cuidados pós-operatórios; Segurança do paciente.

CICLO PDCA PARA ELABORACIÓN DE CHECKLIST DE SEGURIDAD QUIRÚRGICA

RESUMEN: El estudio objetivó utilizar metodología de mejora continua de calidad para elaborar un *checklist* de seguridad quirúrgica para los períodos pre y posoperatorio en unidades de internación. Se realizó investigación participante con dieciséis enfermeras en ocho quirófanos de hospital universitario del sur de Brasil, de marzo 2013 a octubre 2014. La elaboración conjunta del *checklist* estuvo orientada por el ciclo de mejora continua y el Programa Cirurgias Seguras Salvam Vidas. El *checklist* fue sometido a prueba piloto con 450 instrumentos completados y analizados por estadística descriptiva. Luego de ajustes determinados por la evaluación, fue aprobado como "Checklist de Seguridad Quirúrgica Pre y Posoperatoria", con 85 indicadores agrupados en seis categorías: I) Identificación, II) Preoperatorio, III) Posoperatorio Inmediato, IV) Posoperatorio Mediato, V) Complicaciones, y VI) Alta Hospitalaria/Transferencia. El instrumento puede contribuir en acciones preventivas de errores, a monitorear signos y síntomas y a producir indicadores para atención segura del paciente quirúrgico.

DESCRIPTORIOS: Lista de Verificación; Cuidados Preoperatorios; Cuidados Posoperatorios; Seguridad del Paciente.

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● INTRODUCTION

Concern with the quality of care and with patient safety has been the focus of both national and international discussions and considering this, health services need to plan and carry out effective measures to prevent adverse incidents and events during medical care⁽¹⁾. In addition to the population's longevity, technological and scientific advances have resulted in a greater number of surgical interventions, often performed in unsafe conditions⁽²⁾, which predisposes patients to errors that could be prevented.

Among the improvement cycles used, the PDCA, which stands for Plan, Do, Check, and Act towards correction⁽³⁾, is a methodology used to identify problems, monitor the outcomes of the care processes, plan preventive actions, test changes to continuously improve the quality and safety of the health systems, as well as to intervene toward preventing errors and adverse events related to patient safety⁽⁴⁾.

A study conducted in three hospitals in the southeastern region of Brazil identified an incidence of 3.5% of surgical adverse events⁽⁵⁾ while in some countries in Africa and the Middle East this rate can reach 18.4%⁽⁶⁾. Another study conducted in Sweden, upon analyzing 271 adverse events, identified that 26% of these events were related to surgical assistance⁽⁷⁾. These data demonstrate the magnitude of the problem and call for adopting measures to promote quality in care and in surgical safety. It is known that incidents in routine processes done by the multidisciplinary team can be prevented by applying protocols or processes with duplicate checks in the form of checklists⁽⁸⁾.

In this context, the World Health Organization (WHO) created in 2004 the World Alliance for Patient Safety and the recommendation to use a checklist in surgical suites in accordance with the program Safe Surgery Saves Lives. In this environment, the checklist should be applied in three surgical moments: before induction of anesthesia, before the surgical incision, and before the patient leaves the operating room⁽⁹⁾.

Brazilian studies conducted in hospitals in the Northeast, South, and Southeast regions assessed the adherence to the checklist obtaining outcomes of 91.5%, 60.8%, and 89.85%, respectively⁽¹⁰⁻¹²⁾. The relationship between using the checklist and reducing surgical complications and mortality rates⁽¹³⁾ depicts the importance of using this tool in the surgical environment, as well as putting in place policies and strategies for behavioral changes by health care professionals.

There are, however, gaps for using a checklist in pre- and postoperative periods in surgical inpatient units where the checklist of safety items and the application of preventive actions are also fundamental⁽¹⁴⁾.

With this perspective, the guiding question for this study was as follows: Is it possible to use the PDCA cycle to guide preparing the checklist for the pre- and postoperative periods in relation to the safety of the surgical patient? The objective of this study was to use the continuous quality improvement methodology in preparing a surgical safety checklist for the pre- and postoperative periods in inpatient units.

● METHODOLOGY

A participant research conducted between March 2013 and October 2014 in a university hospital in south Brazil in 8 inpatient units: Orthopedics & Traumatology, General Surgery, Digestive Tract Surgery, Urology, Plastic Surgery, Liver Transplant, Pediatric Surgery, and Neurosurgery. The group of participants consisted of 16 nurses, all of them from these units, and included a manager, a supervisor, and assistant nurses.

The inclusion criteria were having worked at least one month in the unit and having a work load of at least 20 hours per week. Participants who did not attend the activities planned (meetings and workshops) were excluded.

The participation trajectory of the nurses for building, using, and practically applying the checklist relied on the PDCA cycle as its guiding factor. The following stages were used for this research: P, D,

and C (Chart 1). Stage A (Act correctively) corresponded to validating the checklist by the committee of specialists and is not part of this manuscript.

Chart 1 - Summary of the PDCA cycle stages. Curitiba, PR, Brazil, 2014

| CYCLE STAGES | OBJECTIVES | ACTIVITIES | PRODUCT |
|------------------|--|--|---|
| PLAN (P) | Disseminate among the nurses the research project, request authorization from the management for its elaboration, invitation to participate, and definition of activities. | Three meetings were held in the months from March to May 2013 with the participating nurses in the hospital's own room. The first meeting had the purpose to raise awareness about Safe Surgery and present the research project. The other two meetings were to prepare the Action Plans. | Preparation of Action Plans |
| DO (D) | Prepare the checklist for the pre-operative and postoperative periods with applicability to the nursing care practice. | Meeting in May 2013 to discuss the responsibilities of safe surgery and then collect and organize suggestions of items to become part of the checklist. Workshop for developing the checklist together based on the proposals arising from the previous meeting. Define the checklist's application in professional practice. These activities took place between June 2013 and March 2014 in one of the hospital's auditoriums. | Preliminary draft of the checklist. Version of the checklist to be applied in professional practice. |
| CHECK (C) | Apply the checklist to verify content and applicability in clinical practice. Perform improvements to the checklist after the test. | Test the checklist in 8 surgical services between the months of March and May 2014. Workshop in June 2014 to discuss the outcomes of the checklist test and approve a new version by the nurses who participated in the research. | Filling out the checklists for surgical safety by the participating nurses. Final version of the instrument to be submitted for validation by the committee of specialists. |
| ACT (A) | This stage corresponded to the validation of the checklist by the Committee of Specialists and was the object of another research. | | |

For Phase C, check content and applicability in healthcare practice of the Pre- and Postoperative Surgical Safety Checklist, the data from the instruments filled out were inserted into a worksheet similar to the checklist's format and analyzed in a descriptive way, presented in absolute and relative frequencies by using as a tool the software Microsoft Office Excel 2013®.

After the execution of this stage, the improvement of the checklist was based on analyzing the data, identifying weaknesses and their possible strengths. Exclusions, additions, and modifications were made of some indicators so that the checklist could include the largest number of safety data and reaching a greater adherence to an institutional reality.

This research followed the principles of Resolution 466/12 of the National Health Council⁽¹⁵⁾ and was approved by the Research Ethics Committee under opinion No. 507,713. All participants were informed of the objectives and methodology of the research and signed an Informed Consent Form.

● RESULTS

Those participating in the research were one nurse manager, one nurse supervisor from the surgical units, and 14 assistant nurses, all female, between 30 and 55 years of age, with an average professional experience of 15 years.

As for the stages of the PDCA cycle, the first one, Plan (P), consisted in holding meetings with participating nurses to identify local problems, set targets, and prepare two action plans: one for preparing the safety checklist for the pre- and postoperative periods and another for evaluating its applicability. The Do (D) stage included carrying out the plans and preparing a version of the instrument to be applied in health care practice. The Check (C) stage included filling out 450 checklists in the 8 surgical inpatient units.

Regarding the profile of the patients of these checklists, 227 (50.44%) were male and 223 (49.56%) female with a predominance in the specialties of Pediatric Surgery and General Surgery with 253 of the records (56.22%). The number of instruments filled out and units that participated in the survey are presented in Table 1.

Table 1 - Checklists filled out according to surgical specialty. Curitiba, PR, Brazil, 2014

| Specialty | n (450) | % |
|-------------------|---------|-------|
| Pediatric Surgery | 135 | 30 |
| General Surgery | 118 | 26.22 |
| Urology | 88 | 19.55 |
| Plastic | 55 | 12.22 |
| Orthopedics | 43 | 9.56 |
| Neurosurgery | 11 | 2.45 |

It can be observed in Table 2 that more than 90% of the indicators related to patient identification (nominated Category I) and of the pre-operative indicators (Category II) were filled out. In Categories III, IV, and V, corresponding to IPO - Immediate Postoperative, MPO - Mediate Postoperative, and Hospital discharge/transfer, respectively, there was a decrease in checking the indicators when compared to the other categories.

Table 2 - Filling out the pre- and postoperative surgical safety checklist by categories and surgical specialty. Curitiba, PR, Brazil, 2014

| Variables | Categories | | | | | | | | | |
|-------------------------|---------------------|-------|---------------------|-------|-------------|-------|-------------|-------|--|-------|
| | I Identification | | II Pre-operative | | III IPO* | | IV MPO** | | V Hospital discharge/ Transfers | |
| | n | % | n | % | n | % | n | % | n | % |
| Specialties | | | | | | | | | | |
| Pediatric (n=135) | 134 | 99.26 | 134 | 99.26 | 88 | 65.19 | 14 | 10.37 | 116 | 85.93 |
| General Surgery (n=118) | 115 | 97.46 | 115 | 97.46 | 100 | 84.75 | 59 | 50 | 89 | 75.42 |
| Urology (n=88) | 85 | 96.59 | 85 | 96.59 | 83 | 94.32 | 88 | 100 | 48 | 54.55 |
| Plastic (n=55) | 55 | 100 | 55 | 100 | 50 | 90.91 | 6 | 10.91 | 42 | 76.36 |
| Orthopedics (n=43) | 40 | 93.02 | 40 | 93.02 | 28 | 65.12 | 28 | 65.12 | 28 | 65.12 |
| Neurosurgery (n=11) | 11 | 100 | 11 | 100 | 6 | 54.55 | 1 | 9.09 | 3 | 27.27 |

* IPO - Immediate Postoperative, ** MPO - Mediate Postoperative

Table 3 shows that of the total 450 applications of the checklist, only 224 (49.78%) were filled out by the patients who remained hospitalized after 24 hours of surgery (Category IV - Mediate Postoperative) with indicators of signs and symptoms predictive of alert for possible surgical anesthetic complications. There were indicators not marked when filling out assessments related to the respiratory, digestive, urinary, cardiovascular, and integumentary systems, as well as the surgical site. Even in this category, the prevalence of patients without alterations resulting from surgery stands out.

Table 3 - Data from filling out the checklist indicators checked during the Mediate Postoperative period. Curitiba, PR, Brazil, 2014 (continues)

| Safety Indicator | N | % |
|---|-----|-------|
| Pain | | |
| No | 123 | 54.91 |
| Yes | 24 | 10.71 |
| Epidural Catheter | 4 | 1.79 |
| PCA Pump | 3 | 1.34 |
| Items not marked | 70 | 31.25 |
| Respiratory System | | |
| Tachypnea | 6 | 2.68 |
| Bradypnea | 5 | 2.23 |
| Hypoxia | 3 | 1.34 |
| No changes | 145 | 64.73 |
| Items not marked | 65 | 29.02 |
| Digestive System and Urinary Tract | | |
| Nausea/Vomiting | 20 | 8.93 |
| Constipation | 19 | 8.48 |
| Hematuria | 7 | 3.13 |
| Diarrhea | 4 | 1.79 |
| No changes | 128 | 57.14 |
| Devices | 10 | 4.46 |
| Items not marked | 36 | 16.07 |
| Cardiovascular System | | |
| Hypotension | 13 | 5.80 |
| Tachycardia | 6 | 2.68 |
| Hypertension | 5 | 2.23 |
| Hyperthermia | 5 | 2.23 |
| Bradycardia | 4 | 1.79 |
| Hypothermia | 3 | 1.34 |
| No changes | 135 | 60.27 |
| Items not marked | 53 | 23.66 |
| Integumentary System | | |
| Pressure Ulcer | 4 | 1.79 |
| Injuries | 3 | 1.34 |
| No changes | 137 | 61.16 |
| Items not marked | 80 | 35.71 |
| Surgical Site | | |
| Drainage | 28 | 12.50 |
| Bleeding | 17 | 7.59 |
| Dehiscence | 4 | 1.79 |

| | | |
|--------------------|-----|-------|
| Signs of Infection | 3 | 1.34 |
| No changes | 133 | 59.38 |
| Items not marked | 39 | 17.41 |

In addition to the stage Check (C) of the PDCA cycle and related to the discussion of the outcomes from applying the checklist and its final version, the workshops with the nurses resulted in assessing the content and applicability, as well as approving the new version. It should be pointed out that there was a need to add a new category called "Complications" in order to enable the tracking of problems arising from the anesthetic-surgical procedure.

Thus, after the adjustments to the instrument and validation of its applicability, this was approved with the title "Pre- and Postoperative Surgical Safety Checklist" (PPSSC) with 85 indicators grouped into 6 categories:

Category 1 - Patient identification: record of nine of the patient's personal indicators.

Category II - Pre-operative: with 13 safety indicators checked before the patient is sent to the surgical center.

Category III - Immediate Postoperative: 13 safety indicators checked within a 24-hour period after the surgery.

Category IV - Mediate Postoperative: includes 29 safety indicators related to pain, the surgical wound, and the physiological systems.

Category V - Complications: 17 indicators for recording postoperative complications after medical diagnosis.

Category VI - Hospital discharge/transfer: four safety indicators related to the patient's general state of health, conditions of the surgical wound, presence of devices, and guidelines for home care and return to the outpatient clinic.

● DISCUSSION

This research made it possible to prepare and evaluate the content and applicability of the "Pre- and Postoperative Surgical Safety Checklist" (PPSSC) guided by WHO precepts for patient safety. The results point to the stimulus for creating safety checklists for other health contexts after a positive evaluation of the surgical safety⁽¹³⁾.

In fact, WHO proposes changes and adaptations of checklists because of institutional variability⁽⁹⁾, contributing to listing strategies and specific approaches to perioperative safety.

An example of this practice was the study conducted at a university hospital in the southeast region of Brazil that standardized the pediatric checklist for safe surgery in the pre-operative period by means of child language and using a recreational format anchored in national and international literature. It also had the contribution and experience of health professionals, researchers, and specialists on this theme⁽¹⁴⁾. This methodology becomes strategic to promote the involvement of a multidisciplinary team for the successful implementation of the surgical checklist⁽¹⁶⁾.

In this research, the actions for building and evaluating the PPSSC allowed sharing knowledge and experiences among nurses from surgical units, as well as brought moments of reflection about the professional reality, the institution with its potential and limitations, as well as the requirements of the National Patient Safety Program launched by the Ministry of Health in our country⁽¹⁷⁾.

The results showed that using the scientific methodology of the PDCA Cycle⁽⁴⁾ for the collective construction of the checklist under the auspices of quality management can contribute to processes that involve surgical patient care and the dissemination of good practices in carrying out safe surgeries. This fact is reinforced in a study that saw a reduction of infections related to health care⁽¹⁸⁾ just as

another research in the Middle East identified a 25% reduction in the occurrence of errors in the pre-analytical phase of laboratory tests⁽¹⁹⁾.

In a quality management methodology such as PDCA, the dimension of safety follows the same principles governing Quality Improvement with the objective of improving the care provided in the work place while being integrated with the monitoring activities for detecting problems, planning preventive measures, as well as performing actions to solve quality/safety problems⁽⁴⁾.

As for the checklist's version, it should be pointed out that the Association of Perioperative Registered Nurses (AORN) proposed a model called Check-in where items regarding the patient's identification and surgical documentation are checked prior to admitting the patient into the operating room⁽¹⁶⁾, similar to what has been proposed in this investigation in Category I: patient identification and in Category II: Pre-operative period.

WHO's Program Safe Surgery Saves Lives recommends that an intervention be performed in the pre-operative phase when the informed consent is obtained, the patient's identification is confirmed, along with the surgical site and the procedure to be performed⁽⁹⁾. These indicators were included in this study's instrument.

As to the profile of the patients, which was identified by applying the checklist in the surgical units studied, a prevalence was observed of elective surgeries in male patients, which was also seen in a Brazilian study carried out in the state of Minas Gerais⁽¹²⁾. General and pediatric surgeries turned out to be the most representative in relation to filling out the instruments by specialties, which may be justified by the demand of patients, number of beds for hospitalization, and days reserved for surgical rooms superior to other surgical clinics in this study.

Furthermore, in the organizational context of the institution used in this research, these services implemented its work processes, organizing, executing, and evaluating the nursing actions in a more structured way since the outpatient appointments for surgical indication, following on to a referral to pre-operative examinations and appointments for approval of anesthesia.

The data related to Category I and Category II reached higher percentages in filling them out. In relation to the indicators of Category III (Immediate Postoperative), Category IV (Mediate Postoperative), and Category V (Hospital Discharge/transfer), there was a smaller percentage in filling them out, but was similar to the outcomes of research on checklist items in the operating room, which showed the best results in the pre-operative stage⁽²⁰⁾.

The results showed that probably the nurses were more concerned and attentive with checking the items prior to referral of the patient to the surgical center. A research conducted in a large hospital in the state of Minas Gerais that analyzed filling out 3,872 items of a perioperative instrument identified that 55% of the indicators in the pre-operative phase were not filled out⁽¹²⁾.

This fact may be explained by the health service routine to refer the patient for surgery by checking data needed for the surgery. However, when postoperative information is included, a need can be seen to raise the awareness of nurses and institutions about its importance.

Specifically regarding filling out Category I of the PPSSC, the correct identification of the patient becomes necessary and valid for the surgical team not to perform procedures erroneously. The same applies to Category II as to marking the surgical site. A study carried out in the northeastern region in Brazil showed a low adherence to demarcating the location to be operated⁽¹¹⁾.

Because of the possibility of the occurrence of surgeries involving wrong location and patient⁽⁹⁾, the nurses will need more attention when filling out the checklist. There is the possibility of adverse events occurring especially if there are no imaging exams as part of the medical record, as seen in the findings of this research.

In relation to Category III and IV regarding the immediate and mediate postoperative period respectively, as for the risks and the occurrence of signs and symptoms of possible complications, the main items were bleeding and drainage at the surgical site, pain, nausea/vomiting, constipation, and hypotension. These changes stem from the fact that the patient becomes more vulnerable, especially to those adverse events of a respiratory, circulatory, and gastrointestinal origin⁽²¹⁾.

In this study, it can be noted that there was a prevalence of complications related to the surgical site, which may be aggravated by the risk of infection when using devices, present in this study in 7.59% of the cases. A study conducted in three public hospitals in Brazil has also identified the prevalence of complications related to the surgical wound, especially infection at the surgical site and dehiscence among the adverse events⁽²²⁾. Infections, in particular at the surgical site, remain as the most common cause of postoperative complications⁽⁹⁾.

Considering the indicators pertaining to hospital discharge (Category V), it can be observed that 95% of the patients received orientations for care in relation to the surgical wounds and care in handling the devices such as using the colostomy and bladder pouch, drains, among other devices. At discharge, a careful evaluation of the patient's clinical status must be performed in order to list the necessary cares to be done at home and thus avoid possible readmissions. Thus, it should be pointed out that using the checklist directs the orientations provided by nurses in planning the self-care of surgical patients, as well as allowing caregivers and family members to give continuity to the care at home⁽²³⁾.

The checklist prepared through the PDCA cycle together with the nurses participating in this study proved to be applicable considering that the safety lists have this characteristic and purpose and are capable of measuring indicators related to surgical intervention and its evolution for helping the multidisciplinary team in making decisions.

● CONCLUSION

The PDCA method is recommended by WHO for the continuous improvement of the quality of health services and the care provided for patient safety and its use in this research made it possible to develop and evaluate in a systematic and participatory way an instrument called Pre- and Postoperative Surgical Safety Checklist - PPSSC, representing one more possibility to ensure nursing care with quality in inpatient units and promoting patient safety since the time of surgical indication until hospital discharge.

Therefore, it is hoped that this checklist shall be capable of being applied in health care practice, adapted to the research institution, and serve to stimulate building instruments in different health care contexts. Furthermore, the instrument enables monitoring the signs and symptoms of alert and the production of quality management indicators with benefits for the patient, the family members, the institution, and society as an instrument for preventing adverse incidents and events resulting from surgical assistance. A limit to this research is that using the PDCA cycle with the aim of guiding the preparation of a checklist was done in only one public education hospital institution.

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