

Patient safety in oncology surgery: experience of the São Paulo State Cancer Institute

SEGURANÇA DO PACIENTE EM CIRURGIA ONCOLÓGICA: EXPERIÊNCIA DO INSTITUTO DO CÂNCER DO ESTADO DE SÃO PAULO

SEGURIDAD DEL PACIENTE EN CIRUGÍA ONCOLÓGICA: EXPERIENCIA DEL INSTITUTO DEL CÂNCER DEL ESTADO DE SÃO PAULO

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ABSTRACT

Patient safety concerns in surgery are increasing. The frequency of surgery-related adverse events and errors is high, and most could be avoided. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) proposed the Universal Protocol (UP-JCAHO) for preventing wrong site, wrong procedure, and wrong person surgery. In Brazil, very few health-care institutions have adopted this Protocol. Thus, there is a need to improve its dissemination and assess its effectiveness. The aim of the present study was to report the experiences of the São Paulo State Cancer Institute (ICESP, acronym in Portuguese) in implementing the UP-JCAHO. The Protocol comprises three steps: pre-operative verification process, marking the operative site and *Time out* immediately before starting the procedure. The ICESP surgical center (SC) has been functioning since November 2008. The UP-JCAHO is applied to all surgeries. A total 1019 surgeries were performed up to June 2009. No errors or adverse events were registered. The implementation of the UP-JCAHO is simple. It can be a useful tool to prevent error and adverse events in SC.

KEY WORDS

Surgery Department, Hospital.
Surgical procedures, operative.
Medical errors.
Safety management.
Sentinel surveillance.
Protocols.

RESUMO

A preocupação com a segurança do paciente em centro cirúrgico (CC) tem sido crescente, devido à elevada frequência de erros e eventos adversos, que muitas vezes poderiam ser prevenidos. A *Joint Commission on Accreditation of Healthcare Organizations* (JCAHO) propôs o Protocolo Universal (PU) para a prevenção do lado, procedimento e paciente errado. No Brasil foram poucas as instituições que o implantaram, sendo necessária a divulgação e avaliação da sua efetividade. O objetivo foi relatar a experiência do Instituto do Câncer do Estado de São Paulo (ICESP) na implantação do PU-JCAHO. O protocolo inclui três etapas: verificação pré-operatória, marcação do sítio cirúrgico (lateralidade) e *TIME OUT*. O CC do ICESP está em funcionamento desde novembro de 2008. O PU-JCAHO é aplicado integralmente a todas as cirurgias. Até junho de 2009 foram realizadas 1019 cirurgias, sem registro de erro ou evento adverso. A implantação do PU-JCAHO é simples, sendo ferramenta útil para prevenir erros e eventos adversos em CC.

DESCRIPTORIOS

Centro Cirúrgico Hospitalar.
Procedimentos cirúrgicos operatórios.
Erros médicos.
Gerenciamento de segurança.
Vigilância de evento sentinela.
Protocolos.

RESUMEN

La preocupación por la seguridad del paciente en centro quirúrgico (CC, siglas en portugués) ha sido creciente, debido a la elevada frecuencia de errores y eventos adversos que muchas veces podrían ser prevenidos. La *Joint Commission on Accreditation of Healthcare Organizations* (JCAHO) propuso el Protocolo Universal (PU) para la prevención de sitio, procedimiento o paciente equivocados. En Brasil, pocas instituciones lo implantaron, haciéndose necesaria la divulgación y evaluación de su efectividad. El objetivo del trabajo fue relatar la experiencia del Instituto del Cáncer del Estado de São Paulo (ICESP) en la implantación del PU-JCAHO. El protocolo incluye tres etapas: verificación preoperatoria, marcación del sitio quirúrgico (lateralidad) y *TIME OUT*. El CC del ICESP está en funcionamiento desde noviembre de 2008. El PU-JCAHO es aplicado integralmente en todas las cirugías. Hasta junio de 2009 fueron efectuados 1019 procedimientos quirúrgicos, sin registro de error o evento adverso. La implantación del PU-JCAHO es simple, y es una herramienta útil para prevenir errores y eventos adversos en el quirófano.

DESCRIPTORIOS

Servicio de Cirugía en Hospital.
Procedimientos quirúrgicos operativos.
Errores médicos.
Administración de la seguridad.
Vigilancia de guardia.
Protocolos.

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INTRODUCTION

The concern with the patient safety is a topic of increasing relevance throughout the world. Literature data indicate that one out of every six hospitalized patients is victim of some sort of error or event, which in most of the circumstances are subject to preventive measures⁽¹⁾.

Adverse events may be defined as any incident associated to the use of medication, equipment, diets or the execution of procedures. Such event is classified as serious whenever it results in death, life threat, significant or permanent incapability, when it requires or extends hospitalization, causes congenital abnormality or needs intervention to prevent permanent damage or incapability⁽²⁾. An adverse event may be also defined as a lesion or unintentional complication probably resulting from care, instead of resulting from the patient's disease, and which results in death, incapability or the extension of the patient's hospitalization period⁽³⁾.

Serious adverse events related to surgery have been grouped into five categories: 1) wrong site surgery, 2) wrong patient surgery, 3) wrong surgical procedure, 4) retention of foreign body inside the patient after the end of surgery and 5) death in the immediate intraoperative or postoperative period in patient classified as ASA I⁽²⁾.

Adverse events may result from complications related to medication, surgical procedures, bed handling, transfers, among others. In a general way, the frequency of errors, depending on the used criteria, varies from 2.9 to 39% of admissions, but from 18 to 83% could be prevented^(2,4). The frequency of the different types of errors varies among the several health institutions. According to a study developed with 30,121 medical records, 27.6% of the errors were due to negligence of the professional, 70.5% resulted in incapability for less than six months, 2.6% in permanent incapability and 13.6% in death⁽³⁾. According to studies developed in Canada and in The United States, the errors associated to surgical procedures were the most frequent, representing 51.4% of 1,133 events identified in Canada and 44.9% in The United States^(5,6). The errors were more frequent in school hospitals than in general hospitals⁽⁶⁾.

The occurrence of adverse events results in an increase of additional costs due to the extension of the hospitalization, readmission, repetition of surgical procedure and death. The percentage of readmission for patients who suffer at least one adverse event in relation to those who do not suffer was 25% versus 17% and the percentage of death was 1.3% versus 9.2%. The patient who suffers an event has 20% and 17% more chance to be readmitted within three months and one month, respectively⁽⁷⁾.

This scenario has justified the proposition of some protocols, by private and governmental institutions, for the

prevention of errors and adverse events related to the surgical procedure. The frequency of errors and adverse events is considered one of the indicators of care quality, being one of the points evaluated by some accreditation processes. In order to guarantee the care quality to the surgical patient, in July of 2003, the *Joint Commission Board of Commissioners (JCAHO)* proposed the Universal Protocol for Prevention of the wrong site, wrong procedure and wrong patient⁽⁸⁻⁹⁾, being also recommended by the *American College of Surgeons*⁽¹⁰⁾. In this same direction, in 2004, the *World Alliance for Patient Safety* was created by the World Health Organization (WHO), which in 2007 started a program aimed at reducing errors and events related to surgical procedures, named *Save Surgery Saves Lives*⁽¹¹⁾. This program, similarly to that proposed by the JCAHO, recommends the use of a checklist for safe surgery that includes some tasks and basic safety procedures.

The Universal Protocol of the JCAHO includes three stages: pre-operative verification, surgery site demarcation and procedures prior to the beginning of the surgery *time out*⁽⁹⁾, which are described as it follows. The WHO protocol, besides presenting the stages proposed by the JCAHO, includes a verification stage in the immediate postoperative period (*sign out*)⁽¹¹⁾. The stages of the WHO are named: *Sign in* (before anesthetic induction), *Time out* (before skin incision) and *Sign out* (before the patient leaves the surgery room).

Stages of the JCAHO Universal Protocol⁽¹¹⁾:

1. Pre-operative Verification: aims to guarantee that all relevant information and documents or equipment are available before the procedure is initiated, that they are properly identified and tagged, agreeing with the

identification record of the patient and consistent with the expectations of the patient and with the comprehension of the team regarding the patient, the procedure and the site of surgery. The lack of information or the discrepancies must be approached and solved before the procedure is initiated.

2. Surgery site demarcation (laterality): aims to identify, without ambiguity, the location in which the surgical procedure must be executed. For procedures involving the distinction between bilateral structures (right and left), multiple structures (such as fingers and toes) or multiple levels (such as in column procedures), the site must be marked so that it is visible after the patient has been prepared.

3. Time out - pause: this stage is fundamental and performed at the surgery room before starting the procedure. It aims to evaluate and assure that the patient, the surgery site, the procedure and the position are right, and that all documents, equipment and information are available. At this stage, the entire process of verification is performed orally, out loud, with the participation of all members of the surgery team, requesting the interruption of any activ-

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ity in the room. The items are read completely and exactly as they are written on the form.

The verification process must be interdisciplinary, having the participation of all members in the team and demanding active communication among all.

The protocol must be initiated by a member assigned in the team and conducted safely in order to avoid errors. The surgical procedure is not initiated until all questions and concerns are clarified. This role is generally performed by the nurse, who may, occasionally, feel a little uncomfortable to insist that the pause is taken right before the procedure is initiated. Nevertheless, the nurses must be loyal and committed to the safety of the patient in his interactions with the surgical team, in order to assure that the final verification takes place (*Time out*)⁽¹⁾.

Safety is one of the basic criteria to guarantee the care quality to the patient. In this context, the adoption of strategies for the reduction of errors and adverse events in Health Institutions is fundamental, especially in oncology, in which many surgeries include broad resections and the wrong identification of the patient may have disastrous repercussions⁽¹²⁾. These errors may be prevented with the implementation of simple and safe measures that must be made public so that Brazilian institutions adopt them. Therefore, the present study had the objective to report the experience of the São Paulo State Cancer Institute - ICESP of the Medical School of the University of São Paulo in the implementation of the Universal Protocol of the JCAHO as safety strategy for the prevention of errors and adverse events related to the surgical procedure.

METHOD

This is a descriptive study of experience reporting. It was developed at the Surgical Center (SC) of the São Paulo State Cancer Institute "Octávio Frias de Oliveira" (ICESP), which is a Health Organization (HO) of the State Health Department of São Paulo, administrated by the Medical School Foundation with the support of the Medical School of the University of São Paulo. The SC has 22 operating rooms and, at this moment, only five rooms are activated with a month productivity of 200 surgeries.

EXPERIENCE REPORT

Implementation of the Universal Protocol

The SC of the ICESP has been operating since November of 2008. As of its opening, the Universal Protocol proposed by the JCAHO has been fully applied to all surgeries. Until June of 2009, 1,019 surgeries were performed and no errors or adverse events occurred.

The implementation project of the Universal Protocol was elaborated by the coordinating nurse of the SC, being

revised and approved by the Nursing Board of Directors and the Care General Board of Directors. It contemplated the description of the Protocol stages, the material resources and the necessary human resources, the instrument used as guide for the execution of the stages (*checklist*) (Appendix 1) and the training content.

Human resources: the execution of the Universal Protocol did not require the additional inclusion of members into the nursing team of the SC, which has 16 nurses, 32 technicians and 14 instrumentation technicians who participate in the process. The daily shift designates one nurse per surgical room, who is responsible for guaranteeing the execution of all Protocol stages. Each surgical room has the average participation of one nurse, one technician and one instrumentation technician. Two technicians participate in case of broad surgeries.

Training: all nurses, nursing technicians, instrumentation technicians, doctors and anesthesiologists. The topics approached were: definition of error and adverse event; profile of errors and events in SC; stages of implementation of the Universal Protocol for the wrong site, wrong procedure and wrong patient; and how to fill out the *checklist*. The performance and knowledge of the professionals were evaluated through open and closed questions, being attributed the concept A, B, C and D. The professionals with concepts A and B were considered qualified whereas the others had to attend the training again until they were approved. Most of the professionals presented an excellent performance and did not report any difficulty in the comprehension of the concepts presented.

Material resources: a dermatological pen was requested to mark the surgery site, as well as the printing of the *checklist* forms with the described stages and signaling plates. The plates measure 30cm x 25cm and are made of washable and plastic material. The *checklist* form is a script that includes all the items that must be verified at all stages of the Protocol since the admission until surgery (Appendix 1). This form was elaborated based on the instrument suggested by the JCAHO⁽¹³⁾.

Protocol Description

The three stages of the Universal Protocol are performed at the SC, as described below:

Pre-operative verification and surgery site demarcation

Once he arrives at the SC, the patient is sent to the admission room, where the nursing team performs all verification procedures. Firstly, the team checks if the patient's name and record, contained in the identification wristband, match with the type of surgical procedure scheduled to be performed, the surgery site and the presence of the patient's signature in the terms of free and clarified surgical and anesthetic consent (TFCC). The TFCC include the patient's full name and information about the surgical and anesthetic risk,

site, type and reason to perform the procedure. These are handed over to the patient at the Pre-operative Risk Outpatient Department by the surgeon and the anesthesiologist, and must be signed both by the patient and the doctors. In case the patient is incapable or under 18 years old, the person responsible for him must sign the TFCC.

Once the patient's documentation is verified, the team requests the presence of the surgeon at the admission room. The surgeon must introduce himself to the patient and mark the surgery site (laterality) with a circle made by dermatological pen. At this stage, the patient is still conscious and must state – not confirm – his name, birth date and surgery site. The doctor who will execute the surgical or invasive therapeutic procedure is entirely responsible for the local identification of the intervention⁽⁸⁾. At this stage, the participation of the nurse is essential in order to guarantee that the surgical sites are marked. The participation of the patient is encouraged.

The surgical site demarcation is mandatory for all surgical procedures, except for: surgery in a single organ, intervention cases in which the location of catheter/instrument insertion is not predetermined, patient's refusal and emergency surgeries.

After the demarcation of the surgical site, the nursing team fills out the *checklist* (Appendix 1), in which they take notes from the medical record regarding the patient's identification, allergies and the surgery site (laterality). Once the document is completed, the team separates the signaling plates according to the collected information (allergies and laterality), and sends them, together with the patient and his medical record, to the operating room. The plates allow the identification of the patient, written with a Pilot pen and in different colors, being the red color used to identify *allergies* and the yellow color to identify *laterality*.

TIME OUT

At the operating room, the nurse and the patient, together with the surgeons and the anesthesiologist, make the verification (*Time out*), before starting the procedure. At this moment, the nurse checks, out loud, in the presence of the surgeons and the anesthesiologist, the following items:

Right Patient: verifies the patient's identification regarding his full name and record number;

Right Procedure: verifies the scheduled procedure at the medical record;

Right Site: verifies if the marked surgery location matches with the scheduled procedure;

Antimicrobial: prescribed according to the protocol preconized by the Commission of Hospital Infection Control of the institution and administrated at the operating room;

Allergies: signaled with identification in safety plates;

Blood Loss Risk: verifies if there will be loss over 500 ml (7 ml/Kg in children) identified in the surgery notice, which the patient takes to the room;

Equipment, material and medication: verifies if all the equipment, materials and medications requested and necessary for the surgery are available at the room and within their expiry date.

Right Documentation: verifies if the consents (anesthesia and surgery) are filled out and if the relevant complementary exams for the procedure are available in the operating room.

Right Position: verifies if the patient is in the correct position according to the procedure to be executed.

Patients are not sent to the operating room without demarcation and the checklist must be completely filled out before the surgery begins. The non-conformity with this requisite results in the postponement of the procedure until all items have been checked. It is the nurse's responsibility to execute this control.

DISCUSSION

The purpose for implementing the Universal Protocol in the SC of the ICESP was to guarantee the safety of the surgical patient through the prevention and reduction of risks. This objective was achieved, since no error or adverse event was identified since the beginning of the activities of the SC, suggesting this Protocol is effective.

The Universal Protocol of the JCAHO, although broadly used, cannot prevent all errors and adverse events related to the surgical procedure⁽¹⁴⁾, which makes necessary the future adoption of new patient safety procedures.

A study developed with 28 American hospitals, which had already implemented the procedures of the Universal Protocol, verified that among 1,153 errors, 62% (n=25) related to wrong surgical site; and among these, thirteen were studied in detail in order to identify the cause-root, being verified that nine involved ambiguities or errors that preceded the patient's arrival at the operating room on the day of surgery. Four cases among these involved errors in the reservation of the operating room; three multiple lesions that were not identified or documented at the pre-operative clinical visit and, therefore, were not present on the term of consent; one was related to the wrong printing of the magnetic resonance image, in which the image was printed for a patient with the same name as the one submitted to surgery; and one was related to the wrong note of the surgery site on the medical record and on the term of consent⁽¹⁴⁾.

Errors and adverse events, whenever identified, must be studied and analyzed in detail. The identification of the causes through the analysis of the cause-root has been effective⁽¹⁵⁾. This process involves an approach based on systems that

examine all the activities in the organization, contributing to the maintenance and improvement of the patient safety, such as the progress in the performance and the administration of risks. These aim to assure that the activities work together, not in an isolated way, in order to improve care and safety.

The prevention of adverse events is a pre-requisite of the patient safety. A policy of zero-tolerance is the only standard that may be ethically justified by health institutions or accepted by patients and by the public. The implementation of these policies may face organizational and cultural barriers, especially from part of the professionals of the SC⁽¹⁶⁾. One of the greatest barriers is the team's lack of training, the non-compliance of the professionals with the protocol and the lack of commitment of the institution⁽¹⁷⁾. Therefore, the continuing supervision and education of all professionals are fundamental, as well as the adoption of the protocol as an institutional policy.

Several procedures for the prevention of the wrong patient, wrong site and wrong procedure have been adopted in other institutions out of Brazil, in agreement with the recommendations of the *American Academy of Orthopaedic Surgery*, *Joint Commission on Accreditation of Healthcare Organizations*, *Veteran's Health Administration*, *Canadian Orthopaedic*, and the *North American Spine Society Associations*. However, according to a systematic review recently developed, there are no evidences on the effectiveness of these safety procedures, which makes necessary the development of future studies⁽¹⁸⁾.

In spite of the need for studies of evidence, the procedures included in the Universal Protocol not only assure the

patient safety but also assist the nursing team in the planning of the preview and provision for the surgeries. The cancellation of surgeries generally occurs due to problems that could be prevented with the Universal Protocol. According to a study developed in the interior of São Paulo, the general rate of surgery cancellation is from 6.3 to 4.0%, 3.5% are due to the patient's refusal, the lack of material and equipment in 75% and the lack of documentation in 10.9%⁽¹⁹⁾.

The ICESP has not been accredited by the JCAHO yet, as a school hospital it is more likely to have a higher incidence of errors, thus, there is a need for the adoption of measures for their prevention. Therefore, even though no error or adverse event related to surgical procedures occurred, the verification stage at the immediate post-operative period is still going to be implemented, according to the recommendation of the World Health Organization, and named *Sign out* (before the patient leaves the surgery room)⁽¹¹⁾.

The experience of the São Paulo State Cancer Institute (ICESP) shows that the implementation of a protocol for the prevention of the wrong patient, wrong site and wrong procedure may be easily executed, being an example for other public and private institutions. The interdisciplinary work of the entire team of the SC is extremely important so that the excellence in the patient care and safety is achieved.

The implementation of a protocol helps to prevent the occurrence of adverse events, since it eliminates the confusion regarding the demarcation and facilitates the communication among the members of the surgical team, being certainly effective in the prevention of errors and adverse events related to the surgical procedure.

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Appendix 1 – Printing of the Admission form of the Pre-operative Room

ADMISSION – SURGICAL CENTER

Date: ___/___/___ Time: _____	Identification: Patient's tag
Medical Diagnosis:	
Procedure to be executed:	

CHECK-LIST

<input type="checkbox"/> Full Record	<input type="checkbox"/> Surgical Demarcation
<input type="checkbox"/> Identification Wristband	<input type="checkbox"/> Hair Removal
<input type="checkbox"/> Pre-anesthetic Evaluation	<input type="checkbox"/> Laboratory Exam
<input type="checkbox"/> Surgical Consent	<input type="checkbox"/> Radiographic Exams
<input type="checkbox"/> Anesthetic Consent	<input type="checkbox"/> Electrocardiography
<input type="checkbox"/> Fasting since: ___/___/___ at ___ h	<input type="checkbox"/> Removal of accessories, prosthesis, dentures, lens and underwear
Nurse/Nurse Technician:	COREN:

TIME OUT

Performed at the surgical room, out loud, in the presence of the surgeon and the anesthesiologist.

<input type="checkbox"/> Right patient: identification of the client (full name and medical record number).
<input type="checkbox"/> Right procedure: verification of the scheduled procedure in the medical record.
<input type="checkbox"/> Right site (marked site according to the scheduled procedure).
<input type="checkbox"/> Antimicrobial (according to the protocol).
<input type="checkbox"/> Allergies (reported by the patient).
<input type="checkbox"/> Blood loss risk (identified by the surgeon at the surgical notice).
<input type="checkbox"/> Right medication, material and equipment (as established by the medical team).
<input type="checkbox"/> Right documentation (anamnesis, physical exam, pre-anesthetic evaluation, term of surgical consent, term of anesthetic consent, complementary exams).
<input type="checkbox"/> Right position (according to the procedure to be executed).
Notes:

Responsible for the Procedure

Nurse	Surgeon	Anesthesiologist
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