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Review Article

Foundations of clinical safety in orthopaedic and trauma surgery

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Abstract
The increase in activity, greater complexity and severity of the patients treated by the Orthopedic and Trauma Surgery Departments (OTS) leads to an increase in adverse events among patients and in their severity.
Aclinical safety plan must be available and the pertinent changes made in the organization in order to have the best introduction of clinical safety in OTS departments.
The Safety Plan should include tools to identify and evaluate health-care risks together with tools that prevent, or at least minimize, harm to patients. Experience has shown that there are many barriers for their introduction. To overcome these, we should introduce a new culture into the OTS departments propelled by exemplary leaders to enable the integration of clinical safety as a key component in health-care activities.
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PALABRAS CLAVE
Seguridad clínica;
Gestión del riesgo;
Prácticas seguras;
Cultura de seguridad clínica

Fundamentos de seguridad clínica en cirugía ortopédica y traumatología

Resumen
El incremento de actividad, la mayor complejidad y gravedad de los pacientes tratados por los servicios de Cirugía Ortopédica y Traumatología posibilitan un incremento de eventos adversos en los pacientes y de su gravedad.
Para la introducción óptima de la seguridad clínica en los servicios de Cirugía Ortopédica y Traumatología es necesario disponer de un plan de seguridad clínica y realizar los cambios oportunos en la organización.
El plan de seguridad ha de constar de instrumentos para la identificación y evaluación de los riesgos sanitarios junto con herramientas que prevengan o, en su defecto, minimicen

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los daños al paciente. La experiencia demuestra que existen numerosas barreras para su introducción. Para superarlas deberemos introducir en los servicios de Cirugía Ortopédica y Traumatología una nueva cultura impulsada por líderes ejemplares que permitan integrar la seguridad clínica como un componente clave de la actividad asistencial.
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Introduction

With the publication in 1999 of the Institute of Medicine's (IOM) report "To err is human",[1] patients' clinical safety (CS) has become the focal point of health-care providers, policy makers, and the population in general across the world. Nevertheless, this renewed interest in CS is not new to Orthopaedic and Trauma Surgery (OTS) departments. Adverse effects associated with drugs, nosocomial infections, defective procedures, and diagnostic or treatment errors have been and continue to be of concern in everyday clinical practice.

In recent decades, OTS services have increased their activity in all areas of the hospital: they have developed major out-patient surgery, as well as new techniques and minimally invasive procedures. All this is associated with greater complexity and severity of the patients being treated. As a result, there has been a major increase in adverse events (AE) in OTS services, many of which have been particularly severe.[2,3]

An adverse event is defined as any unforeseen or potential injury that takes place during the provision of health care, caused by the process of providing medical care and not by the patient's underlying conditions or illness.[4]

The main objective pursued by CS consists in minimizing the risks and possibilities of error, making it easier for things to be done properly and harder for them to be done improperly.[1] For all intents and purposes, any medical act can be associated with some kind of risk, with the resulting potential for injury to the patient.

For an optimal introduction to CS in OTS departments, a CS plan must be integrated into the quality care program and the necessary changes must be made in the organization of the department so that all its members direct their efforts toward working with the highest degree of CS[5] (fig. 1).

Patient clinical safety plan

The purpose of the patient clinical safety plan is to provide risk-free care in response to the principle of primum non nocere. We must therefore have a safety plan with the following aims:

- the identification and evaluation of risks and AE,
- the introduction of methods and tools to prevent or, where this is not possible, to minimize patient injury.

Identification and evaluation of risks and adverse events

We have traditionally identified AE in OTS departments on visiting rounds and at the departments' clinical sessions. Work has also been done on CS issues by the quality assurance boards (mortality, infections, haemovigilance, and pharmacy), as well as in clinical history audits and claims analyses. These continue to be a source of highly useful information that enable us to understand safety problems and, in some cases, their causes.

Nevertheless, CS has developed specific tools for the systematic detection of AE (risks), their evaluation (frequency and severity), and their treatment (set of means and actions to prevent, eliminate, and/or decrease risk). The best known are AE studies, AE reporting systems, and briefing.

Adverse events studies

The pioneer AE study is the Harvard Medical Practice,[6] conducted in 1984 in 51 New York hospitals with a sample of 30,121 patients. Since then, numerous studies have been carried out using a similar methodology. The best known ones are the studies conducted in Utah and Colorado,[7] Quality Australian Heath-Care Study,[8] London,[9] New Zealand,[10] Canada[11] and Spain (ENEAS Study).[12]

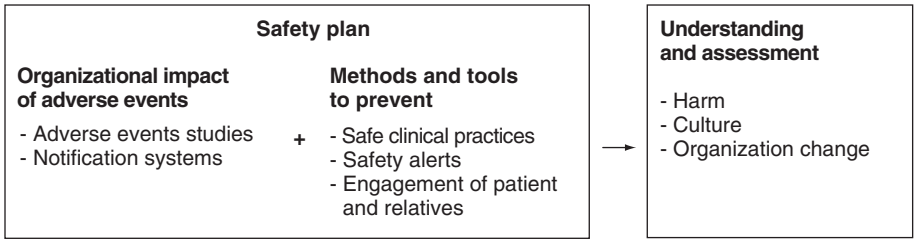

Figure 1 Elements for clinical safety in Traumatology and Orthopaedic Surgery Departments.

Methodologically, these are retrospective cohort case history review studies to determine AEs. They consist of an initial stage at which the nursing staff performs a type of filter that enables them to detect patients that may have suffered some kind of adverse event. In a second stage, the patients detected are re-evaluated by physicians who assess whether or not it is in fact an adverse event and, if so, if it was preventable.

Most of the studies present an AE rate of 3.7-16.6% Approximately half of them are deemed to be avoidable and between 40-60% are related to a surgical procedure. The services with the highest AE rates are general surgery (13.8%) and orthopaedic surgery (12.4%).[8] The operating theatre is the most common place (46.8[8] and 47.2%) for AE in surgical patients, followed by the hospital ward (25.1[8] and 25.8%[7]) More than five percent (5.6%) of AEs caused patient demise, accounting for 12.2% of all in-hospital deaths.[13]

The first population study carried out in Spain (the ENEAS Study in 2005[12] with a review of 5,624 case histories), revealed an incidence of 8.4% of AEs. Of these, 37.6% derived from the surgical procedure; 29.2% from nosocomial infection, and 22.2% were due to medication. Forty-three percent of the AEs were considered to be avoidable. A specific study dealing exclusively with surgical AEs[14] was subsequently carried out. As regards the nature of the main problem, 41.7% were related to nosocomial infection (fundamentally infection of the surgical wound); 27% had to do with the procedure, and 24% with medication. The overall rate of avoidable AEs was 36% Forty percent led to prolonged hospital stay and in 31% the AE was the reason for admission.

All the AE studies identified patient vulnerability factors such as age, co-morbidity, anaesthetic complexity (ASA III-IV), instrumentalization of care, and the application of external devices. These findings point to the need to be more careful in caring for older patients or for patients with more than one pathology.[15]

Although these studies are effective in the estimation of AE incidence, they only detect documented AEs, under-estimating those that are preventable and possibly overlooking serious errors if no injury has ensued.

Notification systems

Notification systems allow the registration of AEs and other incidents affecting patient safety with the aim of analyzing them and learning from them.[16] They are based on experiences in other economic sectors that also have complex organizational structures such as aviation, nuclear power stations and the petrochemical industry.

The philosophy behind its development is based on the iceberg theory. For every AE with serious consequences for the patient, there are countless minor AEs and incidents without consequences for the patient, and these, in turn, share a causal process with countless individual errors and different failures in the organizational system of the company in question.[17]

Notification systems allow us to analyze what happened and why, assess the degree of avoidability and to create new ways of acting so that it doesn't happen again. Medication errors, wrong-site surgery, nosocomial infections, transfusion errors, falls and bedsores are clear examples of the notification of AEs.

Hospital services that have most implemented notification systems are pharmacy, ICU, haematology (transfusions), anaesthesia, surgery and hospitalization. Their experience has highlighted the difficulty for professionals to submit notifications due to their fear of possible disciplinary measures, legal or employment consequences, a sense of guilt regarding the error and excessive workload.[18]

Briefing

Briefing is an Anglicism that is difficult to express in Spanish. "Instruction meeting", "Real-time audit" or "Informative conversation" could all be potential translations. It is defined as a communication based on a multidisciplinary document previously defined in writing on a particular subject. It is used in various sectors including the armed services, aeronautics and advertising. The Johns Hopkins Hospital was the first to adopt it in the medical setting as a strategy to improve patient safety in the surgical area. It can be applied, for example to surgical operations, emergencies involving multiple traumatic injuries (damage control) or cardio-respiratory failures. It can be carried out before or after intervention (briefing/debriefing).[19]

Briefing sessions are led by the surgeon and their main aim is to promote communication among the members of the surgical team in order to analyze the problems and/or risks that might arise during surgery (briefing) or that actually came up during the operation and that we can, thus, prevent and mitigate on future occasions (debriefing).[20]

Methods and tools for prevent harm to patients

In recent years, a multitude of clinical practices, regulations and good practice guidelines have been developed in the field of CS as support systems for the departments and to foster a climate of AE risk reduction in health-care practice.[21]

The main international bodies and quality agencies most devoted to disseminating and spreading this knowledge are: the World Health Organization (World Patient Safety Alliance), the Healthcare Research and Quality Agency, Joint Commission International Center for Patient Safety, Institute for Healthcare Improvement, the National Quality Forum, National Patient Safety Agency, Avedis Donabedian Foundation (patient CS research centre) and the Ministry of Health and Consumer Affairs (Quality Agency for the National Health System).

Safe clinical practices

A safe clinical practice consists in identifying the safest and most effective clinical trial diagnostic and therapeutic procedures, ensure that these are applied to the individuals requiring them and that they are carried out correctly and without errors.[22] For safe practices to be internationally accepted, they have to be applicable in multiple types of care centres and/or multiple types of patients there must be a high probability of procuring a significant benefit for the wellbeing of the patient if they are fully implemented.[23]

The most classic study in this respect is that carried out by Shojania et al.[24] Following an exhaustive review, they identified and assessed as many as 79 practices with the potential to reduce the onset of adverse events. However, when the criteria of evidence-based medicine were strictly applied, only 11 were seen to be of the highest level (table 1).

Table 2 describes the major safe clinical practices that most benefit COT departments[25] and the international organizations disseminating them.

The safe clinical practice with the greatest international resonance at the moment is the "Checklist for safe surgery".[26] This initiative is included in the World Health Organization campaign launched in June, 2008, called "Safe Surgery Saves Lives". It comprises 19 questions that are completed in 3 phases: prior to the induction of anaesthesia (sign in), just before the incision is made (time out) and before the patient leaves the operating theatre (sign out). Each of the items on the checklist must be confirmed orally by one of the team members. The goal is to ensure that the surgical team has understood the surgical procedure to be performed and that the following evidence-based interventions have been carried out: execution of the surgery on the correct patient assigned, with the correct procedure and in the correct place; to encourage the marking of the are to be operated on to avoid laterality errors; application of known methods to prevent AEs in anaesthesia; acknowledgement and effective preparation of patients at risk of haemorrhage; detection and prevention of allergic reactions prior to the induction of anaesthesia; application of correct antibiotic prophylaxis; to ensure the correct positioning of the on the surgical table; to ensure the sterilization of material and equipment; to ensure the remission of correctly identified samples and to guarantee safety through an inventory of swabs, material and instruments used.

A multi-centric study of its application has recently been published and shows a reduction of 47% in deaths and 36% in hospital complications.[27] In the light of these results, several countries such as England and Wales are studying the regulatory incorporation of the checklist in the near future.

Safety alerts

Safety alerts are generally triggered by the information provided by the AE notification systems. They are intended to call attention to certain incidents requiring special attention for their potential impact on patients and the possibility of their being prevented.

In Spain, the most outstanding centres for such alerts are the Research Centre for the Clinical Safety of Patients and the Institute for the Safe Use of Drugs. The Research Centre for the Clinical Safety of Patients currently has 8 active alerts.

These alerts describe the circumstances contributing to their onset and the measures designed to prevent their repetition. Some of the alerts in place are: inadequate identification of patients, patient with under-assessed traumatic injuries at ER, risk of intravenous potassium, surgery on the wrong side, precautions for the immobilization of patients and safe administration of drugs.

One of the alerts currently being worked on most in OTS departments is wrong-site surgery.[28] This is defined as surgery performed in an anatomically incorrect location. It may refer to wrong side (left or right limb), to the incorrect position or level (incorrect finger on the correct hand) or to the incorrect procedure (incorrect surgical procedure on the correct finger).[29] Wrong-site surgery is an infrequent

Table 1 Safe practices with the maximum degree of evidence

Prevention goal	Safe practice	Complexity
Deep vein thromboembolism	Adequate prophylaxis	Low
Cardiac complications during surgery	Peri-operative use of beta-blockers	Low
Infections associated with the use of central venous catheters	Use of sterile barriers during the placement of central venous catheters	Low
Infections of the surgery site	Adequate peri-operative antibiotic prophylaxis	Low
Losses and lack of understanding of the informed consent document	Ask patients if they want to revoke or reiterate what was indicated in the document	Low
Pneumonia associated with mechanical ventilation	Continuous aspiration of sub-glottal secretions	Medium
Bedsores	Use of special mattresses	Medium
Morbidity due to the insertion process	Use of ultrasounds as a guide during the insertion of central lines	High
Effects due to the continued use of oral anti-coagulants	Self-monitoring by out-patients	High
Morbi-mortality in critically-ill and surgical patients	Adequate nutritional provision, with emphasis on enteral nutrition	Medium
Infections associated with the use of central venous catheters	Use of central venous catheters impregnated with antibiotics	Low

Taken from: Shojania KG, Duncan BW, McDonald KM et al. Making Health Care Safer: A Critical Analysis of Patient Safety practices; Evidence Report/ Technology Assessment: Number 43. Rockville, MD AHRQ Publication no. 01-E058, 200124.

Table 2 Main safe practices in traumatology and orthopaedic surgery

Safe practice	International bodies with programmes
Safe surgery saves lives. Use of checklists for safe surgery at three key moments: before the induction of anaesthesia, prior to the incision and before the patient leaves the operating room	WHO
Wrong-site surgery: protocol with pre-operative marking clearly indicating the surgical area	WHO; CISP*, NPSA; NQF; JCAHO; Royal College of Surgeons of England; American Academy of Orthopaedic Surgeons
Prevention of surgical infections. Implementation of clinical protocols and guidelines based on scientific evidence	IHI; JCAHO; NQF; Disease Control and Prevention
Venous thromboembolism. Introduction of guidelines for the detection of patients at risk for the administration of prophylaxis and mechanical prevention measures	NQF; AHRQ; NICE; American College of Chest Physicians (ACCP)
Effective assessment of patients with traumatic injuries at the Emergency Room. Application of an advanced life support protocol for trauma cases	CISP*, JCAHO
Hospital falls. Use of adequate restraining material and training of health-care personnel	CISP*; NPSA; JCAHO
Bedsores. Assessment of risks and application of good practices	NQF; JCAHO
Patient participation. Ensure the patient's active participation and involvement in the decisions taken about their health	WHO, JCAHO; AHRQ; university of patients

AHRQ: Agency for Healthcare Research and Quality; CISP: patient safety research centre; IHI: Institute for Healthcare Improvement; ISMP: Institute for Safe Medication Practices; JCAHO: Joint Commission on Accreditation of Health Care Organizations. NICE: National Institute for Health and Clinical Excellence; NPSA: National Patient Safety Agency; NQF: National Quality Forum; WHO: World Health Organization.

*Promoted by the Avedis Donabedian Foundation.

adverse event, easily preventable and very relevant in terms of the potentially severe consequences for the patient and the huge media and legal impacts. The American Academy of Orthopaedic Surgeons suggests that an orthopaedic surgeon runs a 25% risk of performing surgery in a mistaken site on at least one occasion over a 35-year career. The most frequent problems arise in the lower limbs and in spinal surgery. Some risk factors are urgent operations, time pressure to begin or end the surgical procedure, the intervention of several surgeons and the presence of multiple surgical processes in a single patient. Safe practices campaigns recommend the implementation of a protocol with pre-existing marking prior to the operation clearly indicating the surgical area. This protocol has to be accompanied by adequate and effective communication between the team members and a more proactive attitude by patients in the fulfilment of the instructions designed for the prevention of wrong-site surgery.[30]

Implication of patients and their settings

Another tool considered to be of key importance for CS is the change of attitude among patients regarding their illness. Patients have to play an active role in improving their own safety by obtaining information and engaging fully in their care and taking an active part in the decisions about their treatment.

Many initiatives are under way in US hospitals to spread the word about the importance of getting patients to buy in to their illness and care. These initiatives have created informative leaflets and web pages targeting patients to inform them of the basic actions they have to undertake on CS matters. These initiatives usually include information such as the need to remind health professionals treating them to wash their hands, enquiring about who is ultimately responsible for the care given to them, request regular information about their health status and progress, keep a list of drugs habitually taken and another list of those they must not take, understand procedures to prevent falls, etc. One nationwide initiative is that of the University of Patients of the Josep Laporte Library.[31] Under the slogan: "We are moved by health. We accompany our physician", it has developed a tool that provides very simple advice and reminders to organize better their visits to the doctor. There are also specific initiatives to encourage patients to engage with their own safety when facing a surgical procedure. Fundamentally, they are recommended to ask questions of the personnel looking after them so that there are no doubts before or after being subjected to a surgical operation.[32]

Many other initiatives are also emerging for patients, with their own experiences and opinions, to help reduce the AEs in health systems.[32]

Effective communication

In the analysis of the AEs notified to the Joint Commission, communication has been identified as the most common cause of Aes.[32] Effective communication is not merely the transmission of information, but the correct understanding of the message.[33] The personality of the sender and the recipient, the setting in which it takes place and the way it

takes place are decisive factors for communicative effectiveness. In health-care contexts, we have to distinguish between the information shared among professionals and that communicated between professionals and patients.

Open and objective communication between team members has given very good results in other sectors such as aviation and we can also apply it to our departments. Briefings and checklists are clear examples of safe practices stemming from improved communication within the team.

With respect to communication between professionals and patients, it is very important to convey to patients all relevant information truthfully and in line with their requests for information and using a language suited to their level of understanding. In Spain, the basic legislation regulating patients' autonomy and their rights and obligations with regard to information and clinical documentation is Law 41/2002, published in the Official Gazette nº 274, dated November 15th, 2002). This law regulates the informed consent that must be given in writing for surgical operations, invasive diagnostic and therapeutic procedures and aimed at informing patients about the risks and consequences that might have a negative impact on their health.[34]

Impact on the organization

The experience accumulated in recent years shows that it is not easy to introduce CS into our organizations. The lack of managerial leadership and financial resources, limitations on infrastructures, scant integration of risk management, a poorly developed culture of patient safety and resistance to change are some of the obstacles detected.[25,28]

Overcoming these problems is a complex process requiring time.[33] A new safety culture driven by exemplary leaders together with a change in the organization are the key elements for the integration of CS as key component in our day-to-day activities.

A new clinical safety culture

Culture is defined as the predominant set of values, attitudes and behaviour characterizing the operation of a group or organization.[35] In hospitals today, the dominant culture is one in which CS is a subsidiary component of quality. The predominant behaviour is based on sweeping mistakes or errors under the carpet, reacting to adverse effects after the event, individuality and depersonalization of health-care provision through a greater focus on professionals and technology rather than the patient and on identifying culprits to blame for the error.[36] The first step to improve safety is to change this pattern towards a new CS culture in which errors are considered as a consequence of the interaction of multiple factors (what happened?, how?, when?, why?, what must be done so that it doesn't happen again?), and not a question of personal blame (who?). professionals providing health-care must feel comfortable working in a team, without negative hierarchical constraints, and with ongoing communication between the members. This new working climate has to facilitate the development of behaviours such as the ability to acknowledge, communicate and learn from errors, and the humility to ask for help from the rest of the group when individual circumstances make this advisable.

Effective leadership

Leaders are central for the implementation and maintenance of the effectiveness of clinical departments. They must be able to identify areas of improvement, analyze the various options and implement them.[37] In CS, it is essential to have leadership that helps "followers" to develop behaviour, tools, habits, processes and technologies that improve CS outcomes.[38]

An exemplary leader performs three basic activities: 1) develop a will to support CS constantly and visibly; 2) ensure access to ideas about best clinical practices and support processes, and 3) enable their introduction into the organization and monitor their execution persistently.[39]

Organizational change

All the elements mentioned so far will help us introduce CS into OTS departments. But for this to happen harmoniously and definitively, we have to integrate CS into all levels of the organization and create the structures needed for its support and continuity in the organization (Clinical Risk Management Unit, CRMU).

By integration of CS, we refer to the fact that all health-care personnel must be working for and with CS. Aspects such as stress, loss of sleep and personal gestures are known to increase the number of errors occurring, so we must all put in our grain of salt so that errors don't happen. This means we must have professionals with the know-how, attitudes, values and communication abilities aimed at knowing when to apply the best evidence available, and awake to the fact that constantly seeking better quality in their work is a hallmark of a excellence in professional performance.[21]

Although it is essential for all the professionals to buy into the concepts of CS and to work with these, we need to have a structure that helps us succeed in this ambitious project.[33] The most developed tools, in hospital settings in the United States and the United Kingdom, are CRMUs. Their main goals are the development, implementation and monitoring of tools for the detection of AEs (notification systems, safety indicators ...)[5] and the implementation of tools for clinical risk analysis and management (safe practices). They also provide support and advice for the health-care personnel with regard to any CS problem.[33]

OTS department and institutes should be organized following the principles of the best safe practices, using appropriate tools and methodologies for the encouragement and development of CS and patient care, with the support of a multidisciplinary CRMU that can ensure the organizational and cultural change this entails. Such a CRMU must include the participation of both medical and nursing personnel as well as staff from other areas relating to the speciality and any other professionals who can contribute to its goals, such as professionals from the

Centre's Quality Unit, Legal Department or Communications Office.

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