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UPDATE IN INTENSIVE CARE MEDICINE: CRITICAL PATIENT SAFETY

Patient safety in the intensive care department

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Abstract Patient safety is a priority for all healthcare systems. Despite this, too many patients still suffer harm as a consequence of healthcare. Furthermore, it has a significant impact on family members, professionals and healthcare institutions, resulting in considerable economic costs. The critically ill patient is particularly vulnerable to adverse events. Numerous safe practices have been implemented, acknowledging the influence of human factors on safety and the significance of the well-being of professionals, as well as the impact of critical episodes at hospital discharge on patients and their families. Training and engagement of professionals, patients and families are of paramount importance. Recently, artificial intelligence has demonstrated its ability to enhance clinical safety. This update on ''Patient Safety'' reviews all these aspects related to one of the most pivotal dimensions of healthcare quality.

PALABRAS CLAVE
Evento adverso;
Seguridad del paciente;
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calidad;
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La seguridad del paciente en los servicios de medicina intensiva

Resumen La Seguridad del Paciente es una prioridad de todos los sistemas sanitarios. A pesar de ello, todavía son demasiados los pacientes que sufren daños derivados de la atención sanitaria. Además, afecta a los familiares, a los profesionales, y a las instituciones sanitarias, con un coste económico muy elevado. El paciente crítico es especialmente vulnerable a sufrir eventos adversos. Se han puesto en marcha numerosas prácticas seguras, reconocido el papel de los factores humanos en la seguridad, así como la importancia del bienestar de los profesionales y el impacto del episodio crítico al alta hospitalaria en pacientes y familiares. La formación y participación de los profesionales, pacientes y familias son fundamentales. Recientemente la

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inteligencia artificial ha mostrado su capacidad de aportar valor en la seguridad clínica. En la actualización sobre 'Seguridad del Paciente' se revisan todos estos aspectos relacionados con una de las dimensiones más relevantes de la calidad asistencial.

Patient safety (PS) is one of the key elements of healthcare quality. Since the publication of the report ''To err is human''[1] in 1999, many efforts have been made by different national and international organizations and healthcare institutions to reduce the risks associated with patient care.[2] Despite this, still too many patients suffer adverse events (AEs), with important negative consequences for both them and their families, the professionals, institutions and society as a whole.[3] The recent SARS-CoV-2 pandemic has highlighted the high risk of preventable AEs, particularly in the field of Intensive Care Medicine, stressing the fact that the standards of care can change in critical situations with limited resources and high demands.[4,5]

Approximately one out of ten patients suffers harm in healthcare, and it is estimated that over three million deaths are attributable to unsafe medical care. As many as 50% of all AEs are preventable. The indirect costs of such harm amount to billions of US dollars annually, potentially reducing global economic growth by 0.7%.[6]

For many years, Intensive Care Medicine as a specialty and the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (*Sociedad Española de Medicina Intensiva, Crítica y Unidades Coronarias* [SEMICYUC]) have shown interest and concern in improving patient safety.[7] In this Update series on ''Safety of the Critically Ill Patient'', the main advances and challenges of risk management in the Intensive Care Medicine Department (ICMD) are addressed. Critically ill patients are particularly vulnerable to AEs due to the complexity of the system in which the care process takes place, the inherent severity of their conditions, the use of invasive treatments and diagnostic procedures, the many drugs administered and the application of technology together with the need for close communication and teamwork, along with the uncertainty and complexity of decision making, some of them of vital importance and related to end-of-life care.[8] In addition, stress, work overload, professional burnout and other related syndromes affect the well-being of the professionals and impact organizations, patient care and outcomes.[9]

Knowing the epidemiology of AEs in the intensive care setting is crucial to improve safety, allowing us to identify and analyze the main risk areas, and establish strategies to prevent and mitigate AEs. The first number of this series is an exhaustive review of the main national and international studies on safety in the critically ill patient. Despite the methodological differences and variability of the reviewed studies, it is clear that many patients suffer AEs, that these are largely avoidable, and have an impact on patient outcomes, with increased stays, more readmissions, and increased mortality and associated costs.[10–12] In 2007, the SEMICYUC, under the sponsorship of the Quality Agency of the Spanish Ministry of Health, carried out the Safety and Risk in the Critically Ill Patient (*Seguridad y Riesgo en Enfermo Crítico* [SYREC]) study, involving the participation of a large number of ICMDs. The study evidenced the high incidence of avoidable AEs and identified the main types of incidents such us errors related with medication, equipment and devices, or the airway and mechanical ventilation.[13] Furthermore, it afforded knowledge about the main contributing factors, many of which were related to the patient but also to individual aspects of the professionals, their working conditions, and training issues.[14] Based on this study, a more specific analysis was made of certain AEs, like medication errors,[15] and other studies were carried out, such as the IVeMVA, focusing on incidents related to mechanical ventilation and the airway.[16] Since 1994, the ENVIN-HELICS registry has generated information on one of the most frequent and serious AEs in the ICMD, namely healthcare associated infections related to the use of invasive devices. In addition, it has highlighted the impact of multidrug-resistant microorganisms or inadequate antibiotic use in this kind of infections.[17]

This series also addresses the concept of safe practice, defined as the practice that follows those recommendations based on scientific evidence that are effective in preventing the appearance of certain AEs and their consequences, and which are reproducible and applicable in certain settings.[18] In the context of intensive care, the Zero projects are of particular relevance, as they have shown to significantly reduce infections associated with the use of devices in patients admitted to the Intensive Care Unit (ICU),[19–21] including those aimed at preventing multidrug resistances.[22] In relation to safe drug use, recommendations have been made to reduce medication errors, such as the incorporation of pharmacists into the intensive care teams, or the use of technologies such as traceability systems, among other measures.[23] Despite all this, there is still much room for improvement in complying with the recommended standards for preventing medication errors in the ICMD[24,25] There are many safe practices applicable to critically ill patients, such as systems for the early detection of patients at risk of worsening in hospital wards,[26] the transfer of structured information,[27] in-hospital patient transfers,[28] the prevention of mechanical AEs associated with the use of catheters,[29] pressure ulcers[30] or falls,[31] among others.

At present, the aim of Intensive Care Medicine is not only to improve survival among severely ill patients but also to reduce the sequelae of the critical episode. Post-intensive

care syndrome (PICS) is defined as the worsening of new onset or of the previous patient condition at the physical, cognitive, or mental levels after having been admitted to the ICU due to serious illness, and which persists beyond acute hospitalization, affecting the return of the patient to routine life. There is increasing published scientific evidence of the impact of this syndrome in the mid and long term. This clinical entity is present a in many critically ill patients (30–50%) and is characterized by physical (mainly respiratory and neuromuscular), cognitive (memory and attention) and psychological sequelae (depression, anxiety, stress and/or posttraumatic stress syndrome) at ICU discharge, which have a negative impact upon patients' quality of life. The syndrome affects the capacity of returning to work, increases the risk of readmissions, persists for a long time, and generates very high economic costs for society as a whole.[32]

Post-intensive care syndrome also affects the patient's families (PICS-F), making them vulnerable to negative physical, psychological and social consequences that lead to a deterioration in their own quality of life.[33] Several studies have reported a high prevalence of anxiety (73%),[34] depression (35%),[35] post-traumatic stress (56%)[36] and complicated grief (52%)[37] among family members of ICU patients. These sequelae may persist over time. In the RECOVER study, 16% of the family members had not reduced their level of depression one year after the patients discharge.[38] In addition, they experienced physical symptoms such as fatigue and health risk behaviors such as sleep disturbances, inadequate rest, lack of physical activity, poor dietary habits, or a lack of adherence to medical treatment. In turn, the burden of caring for a post-critical patient affects personal aspects including life plans, social and professional relationships, and can lead to family conflicts.[39]

This series addresses PICS from the perspective of patient safety, considering its high degree of avoidability, as evidenced by different studies.[40] The concept of ''ICU Liberation''[41] is a life-quality improvement initiative based on the implementation of the ABCDEF bundle that incorporates measures with a high level of scientific evidence, and which has shown that, when globally applied, leads to better outcomes and a reduction in the appearance of PICS. Pain control, adequate sedation, management of delirium, keeping patients awake and breathing spontaneously, early mobilization, and implication and participation of the families are measures that have demonstrated benefit not only in terms of patient survival but also in terms of the patients and families sequelae at ICU discharge.[42] Moreover, other elements related to humanized care have been gradually incorporated: good communication (G) with a vision of the needs of the patient, offering holistic care in a ''like home'' setting (H), and redefining the architectural design of the ICU (I), adapting respiratory strategies on an individualized basis (R), and avoiding malnutrition (N).[43] In addition, the importance of follow-up at hospital discharge is addressed, with recommendations on how to conduct post-ICU visits to detect possible sequelae referred to critically ill patients and their treatment.

Another aspect addressed by this series is the impact that the well-being of healthcare professionals might have on PS. Intensive care professionals work in a very stressful environment that not only affects their physical, psychological and emotional well-being but also other dimensions (e.g., social or occupational), with negative organizational and patient outcome consequences.[44] These factors might lead to professional burnout and other entities such us moral suffering or compassion fatigue. It is thus essential to promote the well-being of the healthcare professionals in the ICU through a multidimensional approach, improving their skills in non-technical areas such as effective communication or teamwork, as well as introducing evidence-based strategies that modify stress factors, increase the resilience of the professionals and contribute to safer and more efficient care.[45]

In this context, it is important to highlight the concept of the ''second victim''. This term was introduced in the year 2000 by Wu[46] in reference to the professional intervening in an unavoidable AE who becomes traumatized by the experience or is unable to emotionally cope with the situation. Scott et al.[47] later expanded the definition, referring to all healthcare professionals intervening in an AE, medical error or some unexpected harm related to the patient, and who become a victim in the sense that they become traumatized by what has happened. A recent systematic review has found that 58% of the professionals in intensive care have experienced second victim syndrome. The most frequent symptoms comprise guilt (12–68%), anxiety (38–63%), anger with oneself (25–58%), and a loss of personal confidence (7–58%). Moreover, approximately 20% of the professionals took over a year to recover or failed to do so in that time.[48]

Different studies have described a series of immediate reactions on the part of these professionals implicated in an AE, as a response to acute stress with symptoms of re-experience (repetitive recall of the episode, dreams, nightmares, intrusive thoughts), alerts (subjective feelings of inadequacy, fear of repeating the mistake) and avoidance, together with feelings of guilt, shame and depersonalization. Some professionals experience affective symptoms (sadness, irritability, emotional lability, confusion, sleep disturbances, lack of concentration) or anxiety. There may be specific cognitions such as loss of confidence, feelings of incompetence, fear of making a mistake, or of losing acknowledgment, reputation or prestige. All this can have middle- to long-term personal and professional consequences, such as toxic substance abuse, changes in attitude towards work, abandonment of the profession, or even suicidal behavior.[49] These consequences may manifest as an initial response to the incident or as a result of the reaction of other professionals, during the investigation procedure, or during the legal process, if this were to occur.[50] Strategies have been described for the support of second victim cases, to be implemented at individual and organizational levels,[51,52] on an immediate basis, and sustained over time. The priority in second victim cases is to offer support and understanding, and to adopt a non-punitive attitude, especially on the part of other professionals or peers, as well as the institutional supervisors. Discussion should be favored, with analysis of the AE to know the causes and apply the changes needed to prevent the problem from happening again. All this is to be done by ensuring confidentiality and facilitating the support of experts and external resources (e.g., legal and psychological), where needed. Although still very few, several second victim supportive initiatives should be developed and extended to cover the needs of the professionals involved in an AE.[53]

The approach to PS and risk management in healthcare has gradually adapted to different conceptual models from different industries. At present, PS should not be anchored in the classical models but should be complemented by innovative advances that allow a comprehensive view of all the key elements and participation of the agents involved in this essential dimension of healthcare quality. Among the main theories and elements that have contributed to understanding and improving PS, mention must be made of the human factors concept, and ergonomics, which are also addressed in this series.

The science of ''human factors'' focuses on the environmental, organizational and occupational aspects, as well as on the human and individual characteristics, that influence the behavior of people at work and may have an impact on health and safety. Ergonomics in turn focuses on the design of workplaces, tools and tasks, seeking to adapt them to the physiological, anatomical and psychological characteristics, and the capacities, of the workers involved. Human working skills, understood as decision-making, communication, teamwork and leadership, situational awareness, and the handling of stress and fatigue, are of fundamental importance in PS. A particularly relevant aspect in this regard is fatigue among intensive care professionals, with long hours of duty and a lack of rest, resulting in an impact upon PS[54] that has recently led to the consideration of replacing the 24-h duty service with other models.

The training of healthcare professionals in specific competencies in PS is another key element for the improvement of safety. The use of clinical simulations and other teaching tools have shown to be useful in acquiring these competencies, including both technical and non-technical competencies (behavioral skills) like teamwork or effective communication. From a practical perspective, the series reviews the concept of clinical simulation and the specific components of a simulated clinical scenario, *in situ simulation*, and other teaching tools such as virtual or enhanced reality and the evidence of the impact upon the training of common techniques and procedures in Intensive Care Medicine.[55] Training in these tools has been encouraged from the SEMICYUC, with the promotion of clinical simulation instructor courses.

In recent years, patient safety as a discipline has increasingly focused on system approaches, which can be more adequate for understanding and improving the modern and complex healthcare systems, and particularly the critically ill patient setting. In this sense, among other initiatives, specific focus will be made to the SEIPS (Systems Engineering Initiative for Patient Safety) model, which is based on interaction among the different elements of a working system (including processes and results),[56] and the Resilient Health Care model, which is based on the principles of resilience engineering. The classical model (Safety I) is a linear construct (if things work and the rules are followed, AEs do not occur; and if they are not followed because of errors, AEs do occur) that focuses on what is not safety and seeks to learn from situations in which safety has been missing. In comparison, Safety II moves away from causality and linear propagation. It is one of the organizational resilience theories introduced by Hollnagel,[57] focused on what has gone well, and on strengthening the capacity to be successful in variable circumstances, in resilience. This series reviews the theories proposed from these other perspectives.

In the last decades, clinical information systems in ICMDs have offered a great opportunity: apart from their impact in primary use in quality and safety,[58] their secondary use constitutes a golden opportunity to measure processes and outcomes in PS, as well as for research.[56,57,59,60] In fact, if quality information is guaranteed, the application of artificial intelligence (AI) models to these data will represent a significant advance over the coming years. AI is a part of many healthcare processes, offering new opportunities, including the improvement of safety. In intensive care, AI could improve the diagnostic and therapeutic capacity in the more critically ill patients. Among the tools based on AI, and particularly deep learning, mention should be made to decision-making support systems, tools for predicting AEs,[61] and tools for safe medication use. However, for them to afford value and become effectively and safely incorporated into practice, it is necessary to deal with several technological, ethical and legal challenges. Cross-discipline work is needed in this regard, involving other professionals – particularly data scientists – in order to establish a roadmap to ensure responsible use of the data generated by the care of critically ill patients. Furthermore, application in clinical practice of the AI models generated from these data will require an adequate transference process from developmental settings to real-life implementation scenarios.[62]

Lastly, but no less importantly, participation of the patients and their families in the safety strategies is reviewed. Although this is regarded as one of the fundamental cornerstones for the improvement of safety, it remains a challenge for many organizations, and the active participation of patients and their families is not frequent.[63] Thus, it is necessary not only to want to implicate them, but also to train them in the detection of incidents, in safe practices, and even in the analysis of AEs and incidents or seek their participation in improvement measures to reduce their incidence.[64] The increasingly common presence of families in the ICMDs, communication, and a strong safety culture, are key elements for effectively integrating the patients and their families in PS.[65] Incorporating the patient perspective in assessing the experience of the care received (Patient-reported experience measures [PREM])[66] and measuring the results accordingly (Patient-reported outcome measures [PROM]), expands the concept of safety, placing the person at the center of the system, where the value of healthcare is measured in terms of the real benefits and outcomes for the patient.[67]

We hope that this new series of the journal *Medicina Intensiva* will contribute to strengthen the importance of PS and offer risk-free care for patients, families and professionals. Because PS is not an option but an essential part of care quality.

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Conflicts of interest

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