



POINT OF VIEW

Patient safety certification in a Department of Intensive Care Medicine: Our experience with standard UNE 179003:2013[☆]



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KEYWORDS

Risk management;
Patient safety;
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Abstract Systematic and structured methods must be used to ensure that healthcare risks are effectively managed. Spanish standard UNE 179003:2013 provides healthcare organizations with a framework and a systematic protocol for managing patient safety from a clinical and organizational perspective. Furthermore, it is useful in securing an efficient balance among health risk, health outcomes and costs. The UNE 179003:2013 certifies that a clinical service complies with rules and operating procedures aimed at reducing the incidence of adverse events. It also requires mandatory continuous improvement, given that the standard entails frequent monitoring of the risk management system through periodic audits.

The aims of this paper are to describe the UNE 179003:2013 certification process in an Intensive Care Unit, propose a risk management program for critical patients, and offer some recommendations regarding its implementation.

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PALABRAS CLAVE

Gestión de riesgos;
Seguridad del
paciente;
Medicina Intensiva;
Certificación

Certificación en seguridad del paciente en un Servicio de Medicina Intensiva: nuestra experiencia con la norma UNE 179003:2013

Resumen Para asegurar que el riesgo asistencial se gestiona de manera efectiva es necesario utilizar métodos sistemáticos y estructurados. La Norma española UNE 179003:2013 ofrece a las organizaciones sanitarias un marco y una forma sistemática de abordar la gestión de la seguridad del paciente desde una perspectiva clínica y organizativa, que contribuye a alcanzar un balance eficiente entre riesgo, resultados en salud y costes. Obtener la certificación con UNE 179003:2013 demuestra el cumplimiento de unas normas y unos procedimientos de trabajo dirigidos a disminuir la incidencia de eventos adversos, y obliga a realizar intervenciones de mejora continua, porque la Norma exige realizar un seguimiento periódico del sistema de gestión de riesgos mediante auditorias regulares.

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El objetivo de este trabajo es presentar el proceso realizado para obtener la certificación por la Norma UNE 179003:2013 en nuestro Servicio de Medicina Intensiva, proponer un programa de gestión de riesgos del paciente crítico y hacer algunas recomendaciones sobre su implantación. © 2013 Elsevier España, S.L. y SEMICYUC. Todos los derechos reservados.

Introduction

Healthcare is always associated with a risk of adverse events (AEs) at all care levels,^{1,2} and particularly in Departments of Intensive Care Medicine (DICMs), due to the seriousness of the condition of the critical patient and the complexity of the provided care.

The incidence of AEs in the SYREC study, carried out in 79 Spanish DICMs, was found to be 29% (interquartile range, IQR: 5–50).^{3,4} These and other data oblige us to introduce practices designed to improve critical patient safety,^{5,6} and which at least contemplate adequate risk management; commitment on the part of the healthcare professionals and management staff to adopt a proactive approach to the use of methods for the identification and analysis of safety problems and the detection of underlying causes; the development of preventive strategies; and reactive learning referred to the observed AEs.

Risk management is based on a well defined method derived from the major company business world and which began to be introduced in the healthcare sector in the United States in the 1960s.^{7,8} Since then, its diffusion has gradually increased worldwide.⁹ In 2010, the Spanish Normalization and Certification Association, through the Normalization Technical Committee (AEN/CTN 179 Quality and Safety in Healthcare Centers, Subcommittee 5 Patient Safety Risk Management), published standard UNE 179003 to help healthcare organizations to implement a risk management system (RMS), consolidate a safety culture, and secure an efficient balance among risk, health outcomes and costs.

The current version of UNE 179003 is that published in 2013.¹⁰ It consists of 6 chapters and three annexes. Sections 4 and 5 are the most relevant parts, and document the requirements for certification (Fig. 1). In this respect, after implementing the RMS, organizations can request their certification, accrediting in writing that they comply with the specific requirements of the mentioned standard, possess a UNE 179003 RMS, and offer safe medical care.

The present study describes the process for obtaining standard UNE 179003:2013 certification in our DICM (the first Department in Spain to do so), proposes a risk management program for the critical patient, presents the first results obtained, and offers some recommendations regarding its implementation.

Implementation of standard UNE 179003:2013

The standard was introduced in the DICM of Hospital Can Misses in Ibiza (Spain), belonging to the *Servei de Salut de les Illes Balears* (Balearic Islands Health Service). Our Department comprises a 9-bed polyvalent Intensive Care Unit (ICU)

in the setting of a 220-bed hospital. The staff comprises a Head of Department, 6 intensivists, a pharmacist with part-time dedication, a Nursing Supervisor, 20 nurses, 15 nursing assistants and 5 hospital orderlies. A total of 650 patients were admitted in the course of the year 2012.

The UNE 179003:2013 was implemented by the multidisciplinary quality and safety work group, with representation of all the professional categories, and with prior training and experience in both areas. Three-hour meetings were held every two weeks during one year. The team informed the rest of the personnel of the Unit about the standard and the project to be developed, and obtained collaboration in drafting the documentation and developing the RMS. A diagnosis of the situation was subsequently established to assess the degree to which our routine functioning abides with the requirements of the mentioned standard, with a view to identifying the gap between current risk management in the Department and management as proposed by the standard.

A strong point in our case was the fact that we already had certification referred to standard ISO 9001:2008, which facilitates implementation of standard UNE 179003:2013, since the structure of both standards is similar (continuous improvement, executive management leadership, documental management system, assignation of responsibilities and competencies, training and awareness-enhancing activities, non-conformities, and corrective and preventive actions, follow-up and measurement of systems, management review and internal audits). Furthermore, such prior certification afforded experience in implementing the RMS and in the internal and external audits. We also had the training received in monographic courses and in the Master of the Spanish Ministry of Health, as well as experience (as pupils and lecturers) in the courses of the SEMICYUC.

As weak points we must mention the need for training in standard UNE 179003 and the fact that the RMS was not documented. The possible barriers facing implementation included the fact that ours was the first Spanish DICM to incorporate the standard, and the lack of training in patient safety on the part of executive management—a situation that complicated leadership in the RMS. Nevertheless, the Managing Director supported the certification of our Unit.

The next step was to address the weaknesses and deal with the barriers detected in two areas: training in standard UNE 179003 and documentation of the RMS. In this respect a semi-physical presence course on patient safety and standard UNE 179003 was designed and imparted among the personnel of the DICM and the hospital management. The policy, objectives, manual and general procedures of the RMS were defined. The process of risk management was included among the processes of the quality management system ISO 9001:2008 (a transverse process affecting the

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