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ORIGINAL

Assessment of the implementation of safe medication practices in Intensive Care Units

M.J. Otero [a,*], P. Merino de Cos [b], I. Aquerreta González [c], M. Bodí [d], E. Domingo Chiva [e], S.M. Marrero Penichet [f], R. Martín Muñoz [a] and M.C. Martín Delgado [g]

a *Institute for Safe Medication Practices (ISMP-Spain), Salamanca University Hospital (IBSAL), Salamanca, Spain*
b *Intensive Care Unit, Can Misses Hospital, Ibiza, Balearic Islands, Spain*
c *Pharmacy Service, Navarre University Clinic, Pamplona, Navarre, Spain*
d *Intensive Care Unit, Joan XXIII Tarragona University Hospital, Tarragona, Spain*
e *Pharmacy Service, Albacete University Hospital Complex, Albacete, Spain*
f *Pharmacy Service, Dr. Negrín Gran Canaria University Hospital, Las Palmas de Gran Canaria, Las Palmas, Spain*
g *Intensive Care Unit, Torrejón University Hospital, Torrejón de Ardoz, Madrid, Spain*

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KEY WORDS
Medication errors/prevention and control;
Medication systems, hospital/standards;
Evaluation of processes, healthcare;
Safety management; Self-assessment programmes;
Intensive Care Units

Summary
Aim: To ascertain the degree of implementation of safe medication practices in Intensive Care Units and to identify opportunities for improvement.
Design: Multi-centre descriptive study.
Scope: Intensive Care Services.
Participants/procedure: Forty Intensive Care Units that voluntarily completed the "Self-assessment questionnaire on the safe use of medicines in Intensive Care Units" between March and September 2020. The questionnaire contained 147 assessment items grouped into 10 key elements.
Main variables of interest: Average score and average percentage of the maximum possible value for the entire questionnaire, the key elements and the assessment items.
Results: The average score for the complete questionnaire in the Intensive Care Units was 436.8 (49.2% of the maximum possible value). No differences were found according to functional dependency, hospital size or type of service. The key elements concerning the recruitment of pharmacists in these units, as well as the competence and training of professionals in safety practices showed the lowest values (31.2% and 33.2%, respectively). Three other key elements relating to accessibility to information on patients and medicines; standardisation, storage and distribution of medicines; and quality and risk management programmes showed percentages below 50%.

* Author for correspondence.
email: mjotero@telefonica.net (M.J. Otero).

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Conclusions: The questionnaire has identified a number of effective safe practices that are poorly implemented in Intensive Care Units and need to be addressed in order to reduce medication errors in the critically ill patient.

KEYWORDS
Medication errors/prevention and control;
Medication systems, hospital/standards;
Process assessment, healthcare;
Safety management;
Self-evaluation programs;
Intensive Care Units

Assessment of the implementation of safe medication practices in Intensive Care Units

Abstract
Objective: To assess the level of implementation of medication safety practices in Intensive Care Units (ICUs) and to identify opportunities for improvement.
Design: A descriptive multi-centre study was carried out.
Setting: Intensive Care Units.
Participants/procedure: A total of 40 ICUs voluntarily completed the ''Medication use-system safety self-assessment for Intensive Care Units'' between March and September 2020. The survey comprised 147 items for evaluation grouped into 10 key elements.
Main variables: Calculation was made of the mean scores and mean percentages based on the maximum possible values for the overall survey, for the key elements and for each individual item for evaluation.
Results: The mean score of the overall questionnaire among the participating ICUs was 436.8 (49.2% of the maximum possible score). No differences were found according to functional dependence, size of the hospital or type of ICU. The key elements referred to the incorporation of clinical pharmacists in these units, as well as the competence and training of the professionals in safety practices yielded the lowest values (31.2% and 33.2%, respectively). Three other key elements related to accessibility to information about patients and medicines; to the standardization, storage and distribution of medicines; and to the quality and risk management programs, yielded percentages below 50%.
Conclusions: Numerous effective safety medication practices have been identified with a low level of implementation in ICUs. This situation must be addressed in order to reduce medication errors in critically ill patients.

Introduction

Medication errors are a major cause of morbidity in critically ill patients. In Spain, in the SYREC study, which was carried out in 79 Intensive Care Units (ICUs), medication errors were the most frequent non-injury incident (31.2%) and the cause of 11.6% of the adverse events recorded[1]. Studies in the United States have found that medication errors in these patients are more frequent than in other hospitalised patients, with a 2-3 times higher risk of causing adverse events and 2.5 times higher associated mortality[2,3]. Several factors contribute to the increased risk of avoidable adverse drug events in ICUs, including: the increased severity of critically ill patients and the complexity of the treatments they require; the use of numerous medications, many of which are high-risk; and the administration of a large number of intravenous medications that require dose calculations and are often administered by continuous intravenous infusion[4,5].

Improving the safety of medicines in ICUs requires a multimodal and multidisciplinary approach[4,5], that facilitates the implementation of specific medication error prevention practices in all the processes that determine their safety. Proactive assessment tools have proven to be very useful in helping healthcare centres to analyse their processes, identify areas of risk and to prioritise the improvement practices to be implemented. The Institute for Safe Medication Practices (ISMP) developed the ISMP Medication Safety Self Assessment® for Hospitals in the USA[6], a self-assessment questionnaire for a comprehensive and detailed analysis of the safety of medicines in hospitals, which has been used in several countries[7-11]. The ISMP-Spain, with support and funding from the Ministry of Health and the technical collaboration of a group of experts from several hospitals, adapted this questionnaire to Spanish healthcare practice, publishing in 2007 the "Self-assessment questionnaire on the safety of the system for the use of medicines in hospitals"[12], which was updated in 2018[13]. Based on this latest version of the document, ISMP-Spain, the Working Group of Pharmacists in Intensive and Critical Care Medicine (FarMIC) of the Spanish Society of Hospital Pharmacy (SEFH) and the Spanish Society of Intensive and Critical Care Medicine and

Coronary Units (SEMICYUC), developed the "Self-Assessment Questionnaire on the Safe Use of Medicines in Intensive Care Medicine Services"[14], in order to provide a specific tool for ICUs to carry out a detailed assessment of the safety of medicines in this particular area, identify critical risk points and, with this information, plan the best practices to be implemented locally at each site so as to minimise the risk of errors.

Once the questionnaire for ICUs was published, SEMICYUC, SEFH and ISMP-Spain decided to carry out a nationwide study to determine the degree of implementation of safe medication practices in ICUs and to identify opportunities for improvement in order to work together to improve the safety of critically ill patients.

Methods

Multicentre descriptive study of the degree of implementation of the safety practices included in the "Self-assessment questionnaire on the safe use of medicines in Intensive Care Units"[14]. It was based on the completion of this self-assessment by those ICUs and Hospital Pharmacy Services that volunteered to participate in the study and completed the questionnaire between March and September 2020.

The study was publicised through the SEMICYUC and SEFH websites and mailing lists. A computer application installed on the ISMP-Spain website was used to record the responses to the questionnaire, thus ensuring the confidentiality of the information.

Questionnaire and evaluation

The "Self-assessment questionnaire on the safe use of medicines in Intensive Care Units"[14] was developed from the latest version of the
"Self-assessment questionnaire on the safety of the system for the use of medicines in hospitals"[12], by a group of experts from SEFH and SEMICYUC, coordinated by ISMP-Spain. Using a Delphi technique with 2 rounds of evaluation, the assessment items of this questionnaire applicable to the field of ICUs were selected and new items from other ISMP tools were also evaluated[15,16]. The ICU-specific questionnaire consists of 147 assessment items, representing specific practices or measures aimed at preventing medication errors. Of these, 103 are items from the general hospital questionnaire, 31 are items adapted to the ICU domain and 13 are new items specific to ICUs. The items are grouped under 10 headings that correspond to the 10 key elements that have the greatest impact on the safety of ICU medicines, according to the ISMP conceptual model.

Completion of the questionnaire must be carried out over a number of sessions by a multidisciplinary team that has to appraise the degree of implementation in the ICU of each evaluation item using a scale with 5 possibilities. The possible responses are:

A. No initiative has been taken to implement this item.
B. This item has been discussed for its possible implementation, but it has not been implemented.
C. This item has been partially implemented in some or all areas, patients, medicines or professionals.
D. This item has been fully implemented in some areas, patients, medicines or professionals.
E. This item has been fully implemented in all areas, patients, medicines and professionals.

The items of the questionnaire are assigned different scores, depending on their effectiveness in preventing medication errors and their impact on the safety of the system as a whole. Option A always scores 0, while the possible scores for options B, C, D or E of the scale are increasing and include various values ranging from a minimum of 0 for option B to a maximum of 16 for option E. In addition, there are a total of 5 assessment items in the questionnaire where the answer has the option of being "not applicable", to take into account situations where a given ICU does not perform the activity referred to in the item (e.g. if it does not have automated dispensing systems). These items are subtracted from the overall tally if the answer is "not applicable".

The multidisciplinary teams of the participating ICU were unaware of the scoring of the items during the self-assessment phase. At the end of this phase, those responsible for each centre recorded the answers in the computer application developed to evaluate and record the responses to the questionnaire and automatically obtained an individualised analysis of their data. This application allows each user to access their own data at any time as well as the aggregated information of the rest of the ICU, so that they can compare their results.

The aggregate analysis of the results of the ICU taking part in the study included the calculation of the average absolute scores obtained for the entire questionnaire, for each key item and for the 147 evaluation items. Percentages were also calculated on the maximum possible values for the entire questionnaire, for each key element and for each assessment item, as these percentages allow comparisons to be made between key elements and evaluation items.

Statistical analysis

A descriptive analysis of the characteristics of the centres taking part in the study was carried out and the scores and percentages of the maximum values achieved for the whole questionnaire were compared across the ICU in the sample, stratified according to their characteristics. The variables considered were: *1)* functional dependency, with the categories of public and private hospitals; *2)* number of beds in the hospital, with the following categories: $\geq$ 500 beds, 200 to 499 beds and less than 200 beds; 3) ICU type, broken down into: multi-purpose and other; and 4) postgraduate teaching or non-teaching activity.

Table 1 Characteristics of the Intensive Care Units participating in the study (n = 40)

Characteristics	Participants	
	n	%
Functional dependency		
National Health System and other public systems	34	85.0
Private (charitable and non-charitable)	6	15.0
Number of beds		
99-199 beds	8	20.0
200-499 beds	15	37.5
≥ 500 beds	17	42.5
Type of Intensive Care Unit		
Multi-purpose	37	92.5
Other	3	7.5
Teaching		
With postgraduate teaching	31	77.5
No teaching	9	22.5
Location of the Intensive Care Unit		
Andalusia	3	7.5
Aragon	1	2.5
Balearic Islands	3	7.5
Castile and Leon	3	7.5
Castile-La Mancha	4	10.0
Catalonia	9	22.5
Galicia	2	5.0
Madrid	5	12.5
Murcia	1	2.5
Navarre	1	2.5
Basque Country	5	12.5
Valencia	2	5.0
Andorra	1	2.5

The mean percentages of dichotomous variables were compared using the Student's t-test. The ANOVA test was used for the number of beds variable. Values of $p < 0.05$ were considered significant.

Results

A total of 39 ICU from 12 autonomous communities took part in the study, also including an ICU from Andorra, with the characteristics shown in table 1. Of these, 20% were hospitals with 99-199 beds, 37.5% had 200-499 beds and 42.5% were large hospitals with 500 or more beds. With regard to the type of ICU, most of these were multi-purpose units and only 3 were other types (2 medical and 1 coronary).

Table 2 shows the overall results obtained for the questionnaire in the 40 ICU as a whole and in the different groups of ICU established on the basis of the characteristics of functional dependence, size of the hospital, type of ICU and teaching activity. The average score of the full questionnaire for the total ICU was 436.8 points, corresponding to 49.2% of the theoretical maximum value, with a wide range of values (20.9%-82.3%). When the percentages were compared to the maximum possible value observed in the different ICU groups, no statistically significant differences were found between the established groups ($p > 0.05$).

Figure 1 represents the average percentages out of the maximum possible value obtained for the 10 key elements in the ICU as a whole, which makes it possible to graphically show those areas that present a higher risk. Elements iii and viii concerning the *inclusion of pharmacists in the ICU and the proficiency and training of professionals in medicines and safety practices* showed the lowest percentages (31.2 and 33.2%, respectively). The key elements relating to the *availability and accessibility of information on patients and medicines* (item i), *the standardisation, storage and distribution of medicines* (item v) and *the quality and risk management programmes* (item x) also showed values below 50% (44.0%; 43.4% and 46.7%, respectively). All other key elements showed percentages above 50%.

The analysis of the results obtained for each assessment item provides information at a more detailed level that can be useful in determining the degree of implementation of specific practices and identifying those that need to be addressed as a priority to improve safety. A thorough analysis of the 147 assessment items would

Table 2 Overall results obtained for the questionnaire in the Intensive Care Units as a whole (n= 40) and in the groups studied

Characteristics	Score		Percentage of the maximum value (%)		
	Average	σ	Average	σ	Range
Functional dependency					
National Health System and other public systems (n = 34)	438.2	103.1	49.3	11.6	20.9-82.3
Private (profit and non-profit) (n = 6)	429.3	89.2	48.3	10.0	34.5-63.2
Number of beds					
99-199 beds (n = 8)	409.7	84.9	46.1	9.5	34.5-59.4
200-499 beds (n = 15)	457.6	89.0	51.5	10.0	20.9-63.7
≥ 500 beds (n = 17)	431.3	116.4	48.6	13.1	32.9-82.3
Type of Intensive Care Unit					
Multi-purpose (n = 37)	444.0	100.6	50.0	11.3	20.9-82.3
Other (n = 3)	349.5	31.6	39.4	3.56	36.1-43.2
Teaching					
With post-graduate teaching (n = 31)	440.1	95.0	49.6	10.7	32.9-82.3
No teaching (n = 9)	425.9	121.9	48.0	13.7	20.9-63.7
Total (n = 40)	436.8	100.1	49.2	11.2	20.9-82.3

σ: standard deviation.

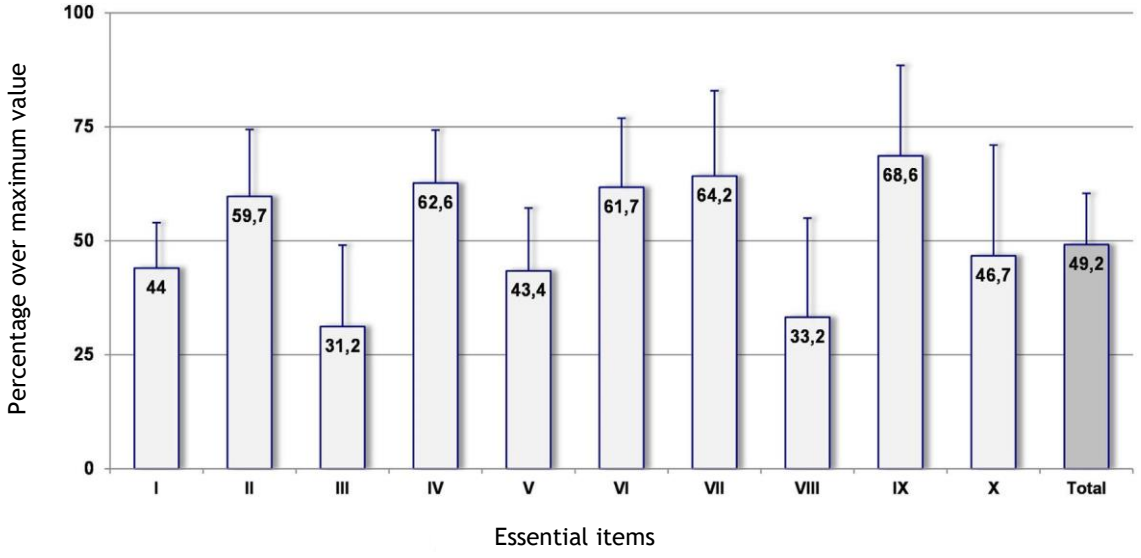

Figure 1 Results obtained in the overall group of Intensive Care Units (n = 40) for the 10 key elements and for the complete questionnaire, expressed as a percentage of the maximum possible value.
Abbreviated description of key elements: I. *Availability and accessibility of patient and medication information. II. Communication of prescriptions and other types of medication information. III. Inclusion of pharmacists. IV. Labelling, packaging and naming of the medication. V. Standardisation, storage and distribution of medication. VI. Procurement, use and monitoring of drug administration devices. VII. Environmental factors and human resources. VIII. Proficiency and training of professionals in medicines and safety practices. IX. Patient and family education. X. Quality and risk management programmes.*

exceed the scope of this article. In tables 3-5 the values identified for several items relating to the incorporation of new technologies, continuity of care and the use of high-risk medicines are shown for illustrative purposes. The full results can be found in a report published by SEFH, SEMICYUC and ISMP-Spain[17].

With regard to the implementation of technologies with an impact on the safety of medicines and which therefore have high maximum values in the questionnaire (table 3), low percentages of 37.5% were found for item 6, which refers to e-prescribing being integrated with hospital information systems, and 43.3% for item 30a, on the

Table 3 Results obtained for the total group of Intensive Care Units (n = 40) for a number of evaluation items related to the inclusion of new technologies

Evaluation item		Score		Maximum possible value	Percentage of the maximum
		Average	σ		
6	Inpatient and outpatient e-prescribing systems are interconnected and integrated into the electronic medical record.	5.21		12	37.5
30a	Electronic prescription systems have clinical decision support systems.	6.93	10.51	16	43.3
15	A code reader is used to verify the medication prior to administration.	0.55	1.43	16	3.4
108	Smart infusion pumps with all safety functions activated are used to deliver, at least, the high-risk medicines.	8.40	6.64	16	52.5

σ: standard deviation.

Table 4 Results obtained for the total group of Intensive Care Units (n = 40) for a number of evaluation items related to the continuity of care

	Evaluation item	Score		Maximum possible value	Percentage of the maximum value
		Average	σ		
17	A complete pharmacotherapeutic history is obtained for all patients on admission to the ICU.	2.30	1.22	4	57.5
18	A standardised procedure is used to reconcile the patient's medication on admission to the ICU.	8.20	6.07	16	51.3
19	A standardised procedure is used to reconcile medication when a patient is transferred from another care unit in the centre to the ICU.	4.65	3.01	8	58.1
20	Upon discharge from the ICU, a standardised procedure is used to inform the following healthcare professionals caring for the patient about the medicines administered, possible adverse effects and proposed medication.	11.40	5.32	16	71.3
96	A standardised line reconciliation procedure is performed at the start of a new shift or upon any intra-hospital transfer of a patient in order to verify all connections.	3.05	2.17	6	50.8

σ: standard deviation; UCI: Department of Intensive Care

availability of clinical decision support systems. The use of a code reader in administration accounted for only 3.4%, while the use of smart infusion pumps, at least for administering high-risk drugs, had a higher value of 52.5%.

With regard to the establishment of standardised procedures to reconcile the medication of patients on admission to the ICU, when transferred from another unit to the ICU or upon discharge from the ICU (items 18, 19 and 20), the average percentages of the maximum possible value determined were 51.3%, 58.1% and 71.3%, respectively (table 4).

Several items related to the safe use of high-risk medicines had low implementation rates (table 5). This is the case for item 82 (11.7%), which refers to vials or

Table 5 Results obtained in the overall group of Intensive Care Units (n = 40) for a number of evaluation items related to the use of high-risk

	Evaluation item	Score		Maximum possible value	Percentage of the maximum
		Average	σ		
24	High-risk medicines are clearly defined and error prevention practices are in place.	2.02	1.54	4	50.5
25	Protocols, guidelines, dosage scales and checklists are available and are used for prescribing, dispensing and administering high-risk medicines.	5.20	2.21	8	65.0
26	Maximum doses for high-risk medicines have been established and incorporated into the software of the technology used (electronic prescription, infusion pumps, etc.).	4.93	3.86	10	49.3
68	Concentrations of infusion solutions for high-risk medicines have been standardised.	3.47	0.90	8	43.4
69	The Pharmacy Service prepares standardised intravenous solutions of high-risk drugs that are not commercially available.	2.53	3.08	10	25.3
82	Vials or ampoules of electrolyte concentrates are not available or are stored separately with additional security measures.	1.40	2.48	12	11.7
85	Neuromuscular blocking agents are stored in separate, labelled boxes.	2.35	3.17	8	29.4
108	Smart infusion pumps with all safety functions activated are used to administer, at least, the high-risk medicines.	8.40	6.64	16	52.5

σ: standard deviation.

ampoules of electrolyte concentrates being removed from ICU or stored separately from other medicines, with additional safety measures. Also item 85, concerning the storage of neuromuscular blocking agents (29.4%), as well as item 69, concerning the preparation by the Pharmacy Service of standardised intravenous solutions of high-risk drugs that are not commercially available (25.3%).

Lastly, item 44, referring to the availability of a pharmacist assigned to the ICU who is part of the care team, for sufficient time to carry out the clinical activities required by the ICU, had

an average score of 5.80 ± 5.27 for a maximum value of 16 (36.3%).

Discussion

In 2017, SEMICYUC and SEFH signed a collaboration agreement with the aim of leading and supporting common initiatives in the fields of care, teaching and research[18]. Among these initiatives, a multidisciplinary approach to the safe use of medicines in critically ill patients, the establishment of recommendations and clinical practice guidelines, and an in-depth study of the epidemiology of medication-related errors and adverse events were agreed upon. The development of the "Questionnaire for self-assessment of the safe use of medicines in Intensive Care Units" and the realisation of this study are the first achievements of this initiative.

The results obtained in this study provide an overall perspective on the safety of the process of using medicines in ICU and reveal that there is significant room for improvement. Although there was a wide range of scores on the full questionnaire across the different ICU in the sample, indicating differences in the degree of implementation of safe practices, analysis of the data showed that there are effective safe practices with very low or virtually no implementation in many ICUs. In our opinion, the information gathered is very useful so that SEMICYUC and SEFH can prioritise the areas in which to focus their efforts to improve the safety of critically ill patients.

Intensive care pharmacists play an important role in the safety of medicines in ICU and evidence supports their

incorporation into multidisciplinary teams in ICU in terms of reducing errors, adverse events and mortality[19,20]. In addition to providing support in clinical decision-making, their functions include involvement in quality assurance programmes to improve the management of medication, participation in the development and monitoring of the implementation of the unit's pharmacotherapeutic protocols, as well as the implementation of new technologies[21]. However, in Spain, the inclusion of the clinical pharmacist in the multidisciplinary teams of the ICU is very limited[18,22]. The results obtained for key item iii of the questionnaire were the lowest (31.2%), again confirming this fact and the need to promote this figure by the SEFH and SEMICYUC.

Element viii, concerning the competence and training of professionals in medicines and safety practices, also showed a low level of implementation, although it is one of the fundamental cornerstones for reducing the risks associated with healthcare[23,24]. The use of training strategies, especially based on clinical simulation, and a multidisciplinary approach is recommended to reduce medication errors in ICUs[25,26], as teamwork and training have been shown to reduce errors and mortality[25,27].

The study highlights the need to promote the adoption of different technologies to reduce prescription and administration errors, which are the most frequent errors in ICU[2-4]. Only half of ICUs have infusion pumps with smart technology to reduce errors in administering incorrect doses or speeds. Only 37.5% and 43.3% have integrated electronic prescription and clinical decision support systems, respectively. It is noteworthy that the use of barcoding in administration, considered the most effective barrier to prevent errors and ensure traceability, is minimal. The development of this technology in Spain has always been hampered by the lack of barcode identification in the unit packaging of medicines.

Other safe practices recommended by the World Health Organisation in its third global patient safety challenge"Medication without harm" and by other organisations are those aimed at reducing medication errors in healthcare transitions and high-risk medicines[26,28,29], common errors in ICU, which are associated with a high risk of harm to patients[30,31]. The survey data indicate that ICU are establishing practices to ensure proper continuity of medication, but that implementation needs to be improved. With regard to safety practices related to the handling of high-risk medicines, the low implementation of practices considered priority or emblematic in patient safety, such as the disposal of potassium chloride vials or ampoules, is striking, which may be attributed to the lack of availability in Spain of concentrated potassium solutions in bags.

As far as we are aware, there are no self-assessment questionnaires available in the field of ICU nor any similar tools, so although it would be desirable, it is not possible to compare the results of this study with others with similar characteristics. Nevertheless, it is worth noting that in the last study on the implementation of safe practices in Spanish hospitals, carried out by 165 centres in 2011, with the initial version of the general hospital questionnaire[32], the lowest values were also obtained for the item related to the competence and training of professionals in medicines and safe practices (29.8%). Although the items in the two questionnaires are not the same, there is no doubt that they relate to measures that are considered to be fundamental for the transformation of health systems and that they are not integrated into Spanish healthcare practice, as discussed above. Other key elements (i, ii, iv, vii and ix) showed slightly higher percentages in this study in the ICUs, probably because various safe practices have been implemented in our country in recent years. In this regard, it is worth noting that item vi, on drug delivery devices, showed a percentage value of 61.7%, compared to 46.7% in the hospital study, indicating that significant progress has been made in this area. Thus, increased use of smart infusion pumps, pumps with free-flow protection systems and specific systems for the delivery of oral solutions and enteral nutrition has been reported.

The study has a number of limitations due to the methodology used. Firstly, the sample may not be representative of the ICUs, as it was not randomly selected. In addition, the number of ICUs participating in the study was lower than initially planned because the study was released shortly before the start of the COVID-19 pandemic, which had such a negative impact on ICUs, and a number of units wishing to participate in the study were unable to do so due to their high and ongoing burden of care. However, the study was completed because its main objective was to identify the most at-risk areas of ICU and the results showed that there were common problems in most of the centres, so we believe that it is possible to generalise the information obtained about the areas most in need of improvement.

Other limitations that should be noted are those inherent in this type of self-assessment tool. Thus, the instructions for carrying out the self-assessment indicate that it should be carried out by a multidisciplinary team with knowledge of the specific situation in the ICU, but no check was carried out to verify this. It should also be noted that there may be some variation in the interpretation of the different items of the questionnaire by the teams formed in each hospital, which may affect the results. Although a pilot test was carried out among the hospitals belonging to the working group to check comprehension of the items in the evaluation, the reproducibility of the questionnaire was not validated.

In conclusion, this study has identified a number of effective safe practices that are poorly implemented in ICUs and need to be addressed in order to reduce medication errors in the critically ill patient. We also believe that this study has promoted the use of the self-assessment questionnaire by ICUs, helping to familiarise professionals with safe practices in the use of medicines and to encourage action at a local level.

Authors

All the authors of this manuscript have contributed to the design and methodology of the study, piloted the questionnaire and contributed to the dissemination of the study. Doctors Otero and Martín Muñoz carried out the preliminary analysis of the data, which were reviewed by all the authors. Doctors Otero and Merino de Cos wrote the first draft of the article. All the authors reviewed the results and contributed to the final version of the manuscript which was approved by all the authors.

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Conflict of interest

The authors declare that they have no conflict of interest.

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List of hospitals participating in the study and co-ordinators in each hospital.

Andalusia: Manuel Colmenero Ruiz, Rocío Morón Romero (San Cecilio University Hospital, Granada); Isabel Caba Porras, Trinidad Vilches Medina (Jaén University Hospital) and Noelia Muñoz Guillén, Asunción Vázquez Castellano (Cordoba Red Cross Hospital).

Aragón: Elena Rebollar Torres, José Ignacio Corchero Martín (Nuestra Señora de Gracia Hospital, Zaragoza).

Balearic Islands: María Asunción Colomar Ferra (Son Espases University Hospital, Palma de Mallorca); Paz Merino de Cos, Fernando Becerril (Can Misses Hospital, Ibiza) and Adriana Martín (Nuestra Señora del Rosario Clinic, Ibiza).

Castile and Leon: Ana María López González, Victor Sagredo Meneses (Salamanca University Hospital); Paola Gon- zález Pérez (Ávila Healthcare Complex) and Caridad Martín López (Segovia Healthcare Complex).

Castile-La Mancha: María Luisa Gómez Grande, Raúl Pérez Serrano (Ciudad Real University General Hospital); Esther Domingo Chiva, José Luís Cortés Monedero (Albacete University Hospital Complex); Marta Fernández Arévalo, María José Sánchez Carretero (Virgen de la Salud Hospital, Toledo) and Aida Rueda Naharro, Estela Gomez Lorenzo (Toledo National Paraplegic Hospital).

Catalonia: Laura Doménech Moral, Ricard Ferrer Roca (Barcelona Vall d'Hebrón University Hospital); Laura María Martínez López, Josep Trenado Álvarez (Mutua de Terrassa University Hospital); Ana Ayestarán Altuna, Josana Fierro Banzo (SCIAS Barcelona Hospital); Mónica Sanmartín Suñer, María Dolores Bosque Cebolla (Catalonia General Hospital); Francisco Fernández Dorado, Montserrat Medina Blanco (Barcelona Diagonal Clinic); Silvia Serdá Sánchez, María Planella Cutrina (Sant Camil Hospital, Barcelona); María Bodí Saera, Laura Canadell Vilarrasa (Joan XXIII University Hospital, Tarragona); Pilar Salvador Collado, Immaculada Vallverdu Perapoch (Sant Joan de Reus Hospital) and Silvia Cano Hernández, María Antonia Balet Duat (Althaia Foundation, Manresa).

Galicia: María Sandra Albiñana Pérez, Enrique Alemparte Pardavila (A Coruña University Hospital Complex) María Sandra Albiñana Pérez, Natalia Mejuto Montero (A Coruña University Hospital Complex, Coronarias).

Madrid: Silvia Manrique Rodríguez, María Luisa Martín Barbero (Gregorio Marañón University Hospital, Madrid); María Luisa Testillano Tarrero, María José Asensio Martín (La Paz University Complex, Madrid); María Cruz Martín Delgado, Marta Blasco Guerrero (Torrejón University Hospital, Madrid); Ana María de Pablo Hermida (Southeast University Hospital, Arganda del Rey, Madrid) and Gema Baldominos Utrilla, Emilio Nevado Losada (Príncipe de Asturias University Hospital, Alcalá de Henares, Madrid).

Murcia: Consuelo García Motos, Maravillas Alcázar Espín (Morales Meseguer University Hospital, Murcia).

Navarre: Amaia Egües Lugea, Joaquín Lobo Palanco (Navarre Hospital Complex).

Basque Country: Ainhoa Quintana Basterra, Sebastián Iribarren Diarasarri (University Hospital of Álava-Txagorritxu); Fernando Fonseca San Miguel, Sergio Castaño Ávila (University Hospital of Álava-Santiago), Elena Zavala Aizpurua (Donostia University Hospital), María Milagros Álvarez Lanvín (Basurto University Hospital, Vizcaya), and Olatz Ibarra Barrueta, Emilia Cámara Quintana (Urduliz Hospital, Vizcaya).

Community of Valencia: Ángel Sánchez Miralles, María Dolores Martínez Juan (Sant Joan University Hospital, Alicante) and Isabel Font Noguera, María Martín Cerezuela (La Fe University and Polytechnic Hospital, Valencia).

Andorra: Antonio Margarit Ribas (Hospital Nostra Senyora de Meritxell, Andorra).

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