



Special article

Standardized classification of pharmaceutical interventions in intensive care units

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ARTICLE INFO

Article history:

Received 19 June 2025

Accepted 29 January 2026

Available online xxxx

Keywords:

Record

Pharmaceutical intervention

Pharmaceutical care

Intensive care units

Critical care

Palabras clave:

Registro

Intervención farmacéutica

Atención farmacéutica

Unidad de cuidados intensivos

Paciente crítico

ABSTRACT

A standardized classification system was developed to harmonize the documentation of pharmaceutical interventions throughout the pharmacotherapeutic process in intensive care units caring for critically ill adult patients. The Intensive Care and Critical Patient Pharmacists Group (FarMIC) created an initial proposal, which was evaluated in a first phase through one week of intervention recording. After analyzing 168 interventions, modifications were made to improve applicability. In a subsequent phase, volunteer hospital pharmacists used the adapted classification for another week, documenting an additional 562 interventions. The analysis of discrepancies and suggestions allowed the consensus of a final classification comprising 35 types of interventions related to issues in indication, effectiveness, safety, and other aspects such as pharmacist consultations, therapeutic drug monitoring, and nutritional support. This classification provides a homogeneous framework that facilitates the standardization of pharmaceutical interventions in critically ill patients and promotes data comparability across centers.

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Clasificación normalizada de intervenciones farmacéuticas en unidades de cuidados intensivos

RESUMEN

Se desarrolló una clasificación estandarizada para homogeneizar el registro de las intervenciones farmacéuticas realizadas a lo largo del proceso farmacoterapéutico en unidades de cuidados intensivos que atienden a pacientes críticos adultos. Para ello, el Grupo de Farmacéuticos de Medicina Intensiva y Pacientes Críticos (FarMIC) elaboró una propuesta inicial que fue evaluada en una primera fase mediante el registro de intervenciones durante una semana. Tras analizar 168 intervenciones, se realizaron modificaciones para mejorar su aplicabilidad. Posteriormente, farmacéuticos hospitalarios voluntarios emplearon la clasificación adaptada durante otra semana, registrando 562 intervenciones adicionales. El análisis de discrepancias y sugerencias permitió consensuar una clasificación final formada por 35 tipos de intervenciones vinculadas a problemas de indicación,

DOI of original article: <https://doi.org/10.1016/j.farma.2026.01.008>.

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<https://doi.org/10.1016/j.farma.2026.03.011>

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efectividad, seguridad y otros aspectos relevantes, como consultas al farmacéutico, monitorización de niveles terapéuticos o soporte nutricional. Esta clasificación proporciona un marco homogéneo que facilita la estandarización de las intervenciones farmacéuticas en el paciente crítico y favorece la comparabilidad de datos entre centros.

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Introduction

Patients in Intensive Care Units (ICUs) are at a higher risk of experiencing drug-related problems (DRPs) and adverse drug reactions (ADRs). A significant contributor to this risk is the high complexity of critically ill patients, characterized by organ damage and the presence of multiple comorbidities.^{1,2} Other risk factors include the high number of medications used –many of which are high-risk medications–, added to the frequent use of parenteral solutions and the complex calculations that individualized dosing involves. Moreover, the clinical workload and frequent medical and nursing staff rotations in these units contribute to increased risk. Finally, continuous pathophysiological changes in ICU patients may significantly influence drug exposure, requiring dose optimization in response to hemodynamic, metabolic, and biochemical variations.^{3,4}

In this context, the clinical pharmacist plays a major role in ensuring medication safety and optimization. The first task of the pharmacist involves validating medical prescriptions by evaluating the medication indicated based on the patient's clinical status and setting. This activity is integrated in the medication use cycle and also includes dispensing and drug counseling, where appropriate, as part of hospital pharmacy services.⁵ Pharmaceutical intervention (PI) refers to any action actively performed by a clinical pharmacist during the therapeutic decision-making and outcome evaluation process. This intervention is considered an opportunity for improvement when it results in an optimized drug therapy.⁶

There is evidence of a two-fold incidence of AEs in the ICU, as compared to the other clinical departments.⁷ The study of reference in Spain, the SYREC study, revealed that 90% of all events and 60% of AEs were avoidable or potentially avoidable, and mostly occurred during the prescribing and administration process.¹ A meta-analysis aimed at assessing the effects of DRPs/AEs in critically ill patients associated them with a longer length of ICU/hospital stay, with no significant differences in mortality.⁸

The evidence available demonstrates that DRP/AE rates in ICUs decrease when the clinical pharmacist becomes actively involved in patient care.^{9,10} Pharmacy activities include investigating the causes of DRPs/AEs and engaging in pharmacotherapeutic decision-making and monitoring.¹¹ The reduction of DRPs/AEs has a significant impact on healthcare costs,^{12–15} particularly when PIs are proactively implemented at the time of prescribing, resulting in enhanced therapeutic effectiveness and efficiency.¹ For these PIs to be implemented, it is necessary that the pharmacist takes part in ward rounds to enable their active involvement in clinical decision making and prevent potentially avoidable events.¹⁶

Overall, 95.4% of ICUs report using an internal medication error (ME) reporting system and/or a regional platform. In 66.7% of cases, these systems allow both the reporters and patient safety managers to access and monitor reported events.¹⁷ In total, 46.4% of hospitals use local reporting systems to report MEs. These findings suggest methodological variability in the evaluation and reporting of pharmacist interventions (PIs), reflecting heterogeneous practices in medication error (ME) management and reporting across ICUs.²

Variability in the use and application of integrated critical care management systems hinders the development of standardized PI classification systems that facilitate improvements in pharmacotherapy and

clinical outcomes. Accordingly, the need arises for a homogeneous, standardized system that enables the accurate classification of PIs in ICUs.

Objective

The objective of this study was to develop a standardized classification system for reporting PIs in ICUs in Spain and assess its applicability to the ICU setting.

Materials and methods

Design: An observational, prospective, multicenter study.

Setting: Spanish hospital pharmacy services providing pharmacotherapeutic review and validation for adult critically ill patients in ICUs.

Inclusion criteria: Adult ICUs including a clinical pharmacist specialized in critical care and a member of the FarMIC working group, which called for voluntary participation in the study.

Exclusion criteria: ICUs attending pediatric and neonatal patients, or hospitals where pharmacotherapeutic review and validation are not performed for ICU patients.

Definition and consensus on PIs: Pharmaceutical interventions were categorized by adapting the proposals from Domingo-Chiva et al.¹ and the “Third Consensus of Granada on Drug-Related Problems (DRPs) and Negative Outcomes associated with Medication (NOM)”¹⁸ to ICU pharmacy interventions. The specialists responsible for this adaptation included members of the Intensive and Critical Care Pharmacy Working group (FarMIC WG) of the Spanish Society of Hospital Pharmacy (SEFH). The FarMIC WG was approved by the SEFH Board of Directors on February 15, 2018 at the initiative of a group of hospital pharmacists that worked very closely with ICUs. This WG is composed of a ten-member coordinating group and its associates, who provide support to WG activities. Any SEFH member can join FarMIC.

PIs were categorized according to their association with indication, drug efficacy, or treatment safety problems, or other problems.

Subsequently, the Microsoft 365[®] Forms app was used to design a Form containing the following fields¹⁹:

Type of intervention (proactive vs reactive): A dichotomous, qualitative variable defined as any recommendation provided by the pharmacist to the medical or nursing staff responsible for a particular patient prior to a DRP (proactive) or after a DRP (reactive).

Medication involved in the PI: A polychotomous qualitative variable. The active substance is recorded. The active substance may be included or not in the Hospital Drug Formulary.

High-risk medication (HRM): A dichotomous qualitative variable in accordance with the considerations from the Institute for Safe Medication Use–Spain.²⁰ HRMS are medications with a very high potential for causing severe or life-threatening harm when used improperly.

Intervention classification: A polychotomous qualitative variable defined as a recommendation provided by the pharmacist to the medical or nursing staff responsible for a patient. Reasons for a PI are defined as the potential causes for which a pharmacist makes a recommendation after having detected improper adherence to clinical

practice when prescribing or administering and transcribing a medication. Pharmaceutical interventions were classified according to the event that prompted the pharmacist's intervention, such as untreated health problems; adverse drug reactions; non-quantitative ineffectiveness; quantitative ineffectiveness; non-quantitative safety issue; and quantitative safety issues, to name a few.

Comments: Free text to record or suggest any other PI that could be of interest and is not mentioned in the Form.

An analysis of the PIs reported during the study period was conducted to further develop a standard classification of PIs in ICUs. The FarMIC coordinating group reviewed discrepancies identified in the records, as well as suggestions received during the Form validation process. Subsequently, this WG consolidated criterion that referred to the same concept, created new types of PIs not included in the original Form, clarified items that caused confusion, and eliminated or reclassified certain interventions into other categories. The Supplementary Material contains a detailed description of the modifications made until a final classification was established, along with a definition for each PI.

Study period: In the first phase of the study, the Form, together with definitions for all types of PIs, was distributed to all FarMIC WG members via e-mail. Participants were invited to record any PIs implemented throughout a week (November 14–20, 2022). The purpose was to verify and ensure the applicability of the Form by introducing modifications that facilitated completion.

In the second phase, the project was presented to FarMIC WG associates, who were invited to voluntarily take part in the validation process. Following acceptance to participate, they received the Form via email. For a week (January 16–22, 2026), all FarMIC members and associates anonymously recorded on the Form any PIs implemented for ICU patients during the pharmaceutical validation process.

Data Source: The clinical pharmacist reviewed the medical records and prescriptions of ICU patients.

Sample size: Sample size was not estimated, as convenience sampling was performed.

Statistical methods: All statistical analyses were performed using STATA v. 14.4. Qualitative variables were presented as absolute frequencies and percentages. An assessment of differences across participating sites was not conducted. Inferential analyses or multivariate models were not performed, as the study had an exclusively descriptive objective.

Results

In the first phase of the study, FarMIC WG members recorded a total of 168 PIs, of which 3 PIs (1.8%) were excluded due to the inclusion of more than one intervention per record. Of the remaining 165 PIs, 36 (21.8%) were classified as "Other". The comments provided by participants led the WG to modify the initial classification.

Based on the PIs that were classified as "Other", this category was redesigned to include new categories, facilitate the reporting of these PIs and avoid missing PI reports during the second phase (see Annex).

During the second phase of the study, a review was carried out of the 609 PIs recorded by 36 pharmacists from 34 national hospitals in 12 different autonomous communities. A total of 47 PIs (7.7%) were excluded for including more than one intervention per record (43 PIs) or due to participants' failure to identify PI type (4 PIs). Following exclusion of the PIs recorded in the first phase, as many as 562 PIs were considered for final validation of the proposed classification system. Interventions were classified by type (proactive vs reactive) (Table 1) and according to the medication involved (high-risk vs low-risk) (Table 2).

Table 3 details the number of interventions recorded according to the final classification system.

Table 1
Categorization of pharmaceutical interventions by type.

Type of intervention	N	%
Proactive intervention (prior to occurrence)	385	68.5
Reactive intervention (following occurrence)	174	30
No recorded	3	0.5
Total	562	100

With regard to intervention-related comments, no comments were received on 403 PIs (71.7%), whereas a brief description was available for the remaining 159 PIs (28.3%). In no case was it necessary to adjust the modified classification.

Discussion

The ICU pharmacist plays a major role in improving the safety and effectiveness of pharmacotherapy. A variety of studies prove that PIs significantly reduce DRPs and AEs in ICUs, resulting in a reduction of mortality, length of stay and duration of mechanical ventilation.^{9,21–27} However, a standard method has not yet been established to evaluate PIs, which limits systematic analysis. This is especially relevant to critically ill patients, for whom a specific PI classification is not available.²⁸

This study confirms the applicability of the protocol previously published by our WG in real practice. This protocol describes the methodological design and preliminary classification of pharmaceutical interventions.¹⁹ To the best of our knowledge, this is the first multicenter prospective study in Spain to use an ICU-specific structured classification system to report and analyze PIs implemented in intensive care units. Previous studies in emergency rooms²⁹ provide evidence that the pharmacist's involvement may contribute to improving patient safety and reducing costs. Additionally, these studies propose different PI classification systems to favor clinical decision-making.

The results of this study pave the way for a standardized classification of pharmaceutical interventions in ICUs based on data from a survey involving 34 hospitals in 12 autonomous communities in Spain. This classification is based on the indication, effectiveness and safety that should characterize pharmacotherapy in critically ill patients, due to their particular characteristics. Indication refers to untreated health conditions requiring additional therapy, either for previously unrecognized indications or for prophylactic purposes, as well as to the inappropriate or unnecessary use of medications for various reasons. Ineffectiveness and safety issues can be categorized as quantitative or non-quantitative. Other specific PIs were included, such as consultations with the pharmacist or the monitoring of plasma drug levels.

A detailed PI classification not only facilitates a thorough analysis of the areas where pharmacy activities may have a greater impact but also provides a useful tool to standardize interventions across hospitals. Our classification system addresses a knowledge gap identified in previous studies,^{30–32} which have highlighted methodological heterogeneity as a barrier to the accurate evaluation and generalization of PI-related outcomes in the ICU. The method used ensures a practical classification that mirrors real clinical practice in ICUs.

The results of our pilot study identified a total of 562 PIs classified into different categories according to the problem detected. Most commonly, PIs were categorized as "Other" (182 interventions; 32.4%), a

Table 2
Categorization of intervention by level of risk of the medication involved.

High-risk medication	N	%
No	387	68.9
Sí	151	26.8
Not reported	24	4.3
Total	562	100

Table 3
Description of the interventions reported.

	N	%
Indication – Untreated health problem	74	13.1
1. Need for additional treatment: untreated indication	24	32.4
2. Need for additional treatment: treatment continuation (reconciliation of omitted drug)	37	50
3. Need for additional treatment: combination therapy (synergy)	5	6.8
4. Need for additional treatment: prophylactic treatment or pre-medication	8	10.8
Indication – Unnecessary medication effect	82	14.6
5. Unnecessary medication: not indicated	9	7
6. Unnecessary medication: a more cost-effective option is available	6	7.4
7. Unnecessary medication: inadequate duration	42	5.1
8. Unnecessary medication: alternative administration route	10	12.2
9. Unnecessary medication: therapeutic duplicity	14	17.1
10. Unnecessary medication: treatment for a preventable adverse drug reaction	1	1.2
Effectiveness – Non-quantitative ineffectiveness (lack of intrinsic efficacy)	25	4.5
11. Improper medication: not indicated for the situation	5	20
12. Improper medication: not effective for that particular indication	5	20
13. Improper medication: improper dosing	14	56
14. Improper medication: a more effective option is available	1	4
Effectiveness – Quantitative ineffectiveness	69	12.3
15. Underdosing: improper dosing/interval (renal failure. Liver failure. Geriatric patient...)	54	78.3
16. Underdosing: inadequate duration	4	5.8
17. Underdosing: inadequate administration	2	2.9
18. Underdosing; interactions (with drugs and/or foods)	3	4.3
19. Underdosing: incorrect dosing/form conversions	6	8.7
Safety – Non-quantitative safety issue	30	5.3
20. Adverse drug reaction: allergy	2	6.7
21. Adverse drug reaction: inadequate administration	2	6.7
22. Adverse drug reaction: adverse event	6	20
23. Adverse drug reaction: contraindicated due to the presence of risk factors	9	30
24. Adverse drug reaction: interactions (with other drugs or foods)	8	26.7
25. Adverse drug reaction: incorrect drug/form conversions	3	10
Safety – Quantitative safety issue	100	17.8
26. Overdosing: inadequate dosing/interval (renal failure. Liver failure, geriatric patients...)	88	88
27. Overdosing: inadequate duration	8	8
28. Overdosing: inadequate administration	0	0
29. Overdosing: interactions (with other drugs or foods)	1	1
30. Overdosing: incorrect dosing/form conversions	3	3
Other	182	32.4
31. Cross-consultation with the pharmacist: dosing, administration. Compatibility...	49	26.9
32. Monitoring of plasma levels (recommendation for monitoring plasma levels for dose adjustment)	55	30.2
33. Pharmacist's recommendation to request a follow-up lab test	5	2.7
34. Pharmacist's instruction to the nursing staff: inadequate dilutions or administration times	23	12.6
35. Intervention regarding nutritional support	50	27.5

category that included consultations with the pharmacy staff, pharmacokinetics monitoring and nutritional support, among others. Indication-related interventions were the second most common type of intervention (156 cases; 27.8%). Overall, 74 corresponded to untreated health problems, primarily involving reconciliation interventions to ensure continuity of pre-existing therapies. A total of 82 PIs were associated with the use of unnecessary medications, frequently due to inadequate treatment duration. Safety-related PIs amounted to 130 cases (23.1%), most of which were due to quantitative safety issues (100), more specifically, overdosing for inadequate dosing or dose intervals. These results are in agreement with the ones reported by Bourne et al.,³³ demonstrating a tendency of treatment safety-related PIs to be prevalent. In the two studies, overdosing or inadequate dose adjustments accounted for a substantial part of pharmaceutical activity. Finally, 94 interventions (16.7%) were associated with effectiveness,

with a stronger presence of quantitative ineffectiveness (69). Within this category, underdosing and inadequate dose intervals were the leading reasons for PIs (54). These findings underline the relevance of PIs in optimizing drug therapies and improving clinical outcomes.

These results are consistent with those reported by Franco Sereno et al.,¹³ who documented a prevalence of PIs related to treatment safety and optimization to improve outcomes, accounting for 33 and 32% of the total, respectively. In other studies, the most common PIs involved dose adjustments based on kidney function³⁰; discontinuance of unnecessary medications³¹; or interventions related to drug-to-drug interactions.³⁴

The high proportion of proactive PIs (69%) highlights the relevance of integrating pharmacists into multidisciplinary teams. Previous studies consistently demonstrate that pharmacists' involvement is crucial for improving ICU care standards and outcomes.^{1,23–25,35–37} Proactive interventions require a previous thorough review of a patient's medical record and prescription orders to evaluate the adequacy, indication and duration of drug therapies, along with interactions, contraindications or duplicate medications.³⁸ In agreement with these findings, other studies underscore pharmacists' involvement in multidisciplinary teams over a logistics-centered approach as the best strategy to improve patient care.^{36,39}

The multicenter design, covering a wide geographical area, represents a major strength of this study. Geographical diversity provides a general overview of pharmacy practices in ICUs in Spain. The participation of 36 pharmacists from diverse hospitals supports the robustness of our findings. This diversity additionally supports the applicability of our classification system in the different situations that may arise across ICUs. In contrast with previous studies conducted in more specific settings or in a single center, our study provides a reference framework that favors data comparability at the national level.^{2,6,9,23–25,35–37,40}

This study, however, has some limitations. Firstly, the study was carried out during a limited period and may have failed to capture the broad variety of PIs that may be implemented at different times or in different clinical scenarios. The FarMIC WG –as the study sponsor– is planning to extend the number of participating sites to account for a wider variety of interventions that may occur throughout a patient's stay in the ICU.¹⁹ Another limitation of the study lies in the evaluators' failure to formally document the consensus process that led to the final definition of the "Other" category, added to the lack of records on the level of agreement among evaluators. This category was maintained to collect heterogeneous interventions (consultations with the pharmacist, monitoring of plasma levels, or nutritional support) that did not fit into the classic categories of indication, effectiveness, or safety, to avoid losing information. The high frequency of PIs categorized as "Other" emphasizes the relevance of these aspects and the need for further reviews that enable a more detailed classification. On another note, since the classification is based on evidence from hospitals in Spain, its international applicability should be assessed considering the structural and organizational differences across national health systems. Nevertheless, this study may serve as the starting point for future adaptations or European multicenter collaborations.

The classification system developed in this study has significant implications for clinical pharmacy practice in ICUs. This tool represents a step forward in the development of a standardized PI reporting system that will help prevent medication errors and reduce healthcare costs. A standard PI reporting system will facilitate data comparability across centers, thereby favoring general improvements to ICU patient care standards. This classification could also be integrated into electronic health record systems, enabling improved real-time data capture and analysis, and ensuring greater consistency and quality of PI reports. Its integration into such systems would further highlight the relevance and practical value of PIs compared with those recorded in external applications or web-based platforms.⁴¹ In the research setting, this classification system provides a valuable tool for the design of multicenter studies aimed at evaluating the impact of PIs on clinical practice,

particularly concerning those PIs for which no specific classification has previously been available.

In conclusion, this study demonstrates the applicability of a standardized classification for pharmacist interventions in ICUs. The proposed classification offers a consistent framework to standardize these interventions, facilitating their integration into routine clinical practice. Its implementation may contribute to improved patient safety, optimization of medication use, and enhanced comparability of data across institutions. Furthermore, its integration into electronic health systems would represent a significant step forward in the monitoring and continuous improvement of pharmacotherapy in critical care settings.

CRediT authorship contribution statement

Esther Domingo Chiva: Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Data curation, Conceptualization. **Fernando Becerril Moreno:** Writing – review & editing, Validation, Methodology, Data curation, Conceptualization. **Miguel Ángel Amor García:** Writing – original draft, Methodology. **Laura Doménech Moral:** Writing – original draft, Validation, Conceptualization. **Tatiana Betancor García:** Writing – original draft, Validation. **Carla Bastida Fernández:** Writing – review & editing, Validation, Conceptualization. **Marta Albanell Fernández:** Writing – original draft, Validation, Conceptualization. **Irene Aquerreta González:** Writing – review & editing, Validation, Conceptualization. **Sara Cobo Sacristán:** Writing – review & editing, Validation, Conceptualization. **Amaia Egués Lugea:** Writing – review & editing, Validation, Conceptualization. **Aurora Fernández Polo:** Conceptualization. **Sara Ortiz Pérez:** Writing – review & editing, Validation, Conceptualization. **María Martín Cerezuela:** Writing – review & editing, Writing – original draft, Validation, Data curation, Conceptualization.

Ethical considerations

The FARMACRITIC study was evaluated and approved as a prospective observational study with medications by the Hospital Universitari i Politècnic La Fe's Ethics Committee for Research on Medications for Human Use on October 25, 2023 (FARMACRITIC sponsor code). Obtaining informed consent from patients was not required, given the observational nature of a study not involving any intervention. The confidentiality and anonymity of any data collected from the patients, professionals and ICUs involved in the study will be ensured in accordance with Organic Law 3/2018 of December 5 on Personal Data and Digital Rights protection. The results of the study will not be directly binding for the professionals and patients involved and will be published regardless of them being positive or negative. This project was presented as an oral communication in the 68th Hospital Pharmacy Conference under the title “National Classification of Pharmaceutical Interventions in Critical Care Units”.

Authorship

All authors are members of the SEFH FarMIC Working Group. All authors took part in the study design and final consensus on the interventions to be implemented. María Martín-Cerezuela, Esther Domingo-Chiva and Fernando Becerril-Moreno were responsible for database management and intervention analysis. María Martín-Cerezuela, Esther Domingo-Chiva, Fernando Becerril-Moreno, Miguel Ángel Amor-García, Laura Doménech-Moral and Tatiana Betancor-García contributed to manuscript drafting. All authors provided critical feedback and approved the final version of the manuscript for publication.

Funding

The authors declare that the standardized classification forms part of FARMACRITIC study, funded by the Spanish Foundation of Hospital

Pharmacy (FEFH) through the 2022–2023 call for Working Group grants.

Conflict of interest

The authors declare no conflicts of interest associated with this project.

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