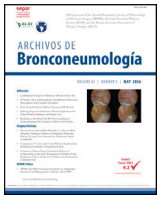
Archivos de Bronconeumología 62 (2026) 509–512

separ
Sociedad Española de Neumología y Cirugía Torácica

ARCHIVOS DE
Bronconeumología

www.archbronconeumol.org



Scientific Letter

## Impact on Clinical Management in an Intermediate Respiratory Care Unit Following Implementation of the ISO 9001:2015 Quality Management System

*To the Director,*

Healthcare systems face increasing clinical complexity, limited resources, and high demand for quality and patient safety. In this context, Intermediate Respiratory Care Units (IRCUs) have emerged as a strategic care model to optimize hospital resources, reduce ICU burden, and facilitate standardized care delivery [1]. However, there are no standardized indicators or validated frameworks to assess their quality and performance. To address this gap, our hospital's IRCU implemented the quality management system (QMS) based on ISO 9001:2015, aiming to optimize safety, organization, and measurable outcomes. ISO 9001:2015, originally designed for industrial applications, has demonstrated benefits in healthcare by improving traceability, standardizing processes, enhancing patient safety, and promoting continuous improvement [2–5]. The primary objective of this study was to evaluate the organizational, process-related, and selected clinical performance impacts of implementing an ISO 9001:2015 Quality Management System (QMS) in our Intermediate Respiratory Care Unit (IRCU), using a before–after observational design comparing predefined indicators from the pre-certification period with post-certification performance. Secondary objectives focused on defining and monitoring quality and performance standards within the unit, with particular attention to patient safety; staff and patient satisfaction; documentation efficiency; equipment maintenance; the perception of the IRCU by collaborating services ("partners"); and continuous staff training and integration of new personnel. Collectively, these objectives aimed to enable an independent evaluation of the IRCU's functioning and to support its formal recognition within the hospital organization, despite the absence of official acknowledgment as a homogeneous functional group (HFG).

Staffing levels, nurse-to-patient ratios, and workforce structure remained unchanged throughout the study period. Categorical variables were compared between the pre-implementation and implementation periods using the Chi-square test. For each comparison, *p*-values, odds ratios (OR), and 95% confidence intervals (95% CI) were calculated to quantify the magnitude and statistical significance of the differences observed. Statistical significance was defined as two-tailed $p < 0.05$. Given that only one pre-certification year was available for comparison, the analyses were primarily descriptive and focused on identifying temporal trends across activity, process, and outcome indicators rather than establishing causal relationships.

The project was developed between October 2022 and December 2024 by a multidisciplinary working group (IRCUs Quality Committee), composed of physicians, nursing staff, and nursing assistants who received specific training on ISO 9001:2015 standards, risk management, and documentation. The implementation followed a structured methodology: An initial gap analysis identified deviations from ISO requirements. The functional scope of the management system was defined, limited exclusively to the IRCU and a specific Quality Policy aligned with the hospital's strategy was developed and diffused through posters and in the hospital intranet. Internal and external organizational context analysis (SWOT analysis) was conducted to assess the initial situation, which helped to identify key stakeholders—patients, families, staff, hospital management, partners, and suppliers—whose needs and expectations guided improvement actions [6,7]. Processes were categorized as strategic (hospital management), operational (care delivery), or support (resources and infrastructure), each with defined inputs, outputs, and responsibilities. Patient safety was integrated transversally. All processes were supported by detailed technical documentation, including Standard Operating Procedures (SOPs), records, and flow diagrams.

Process-related risks were assessed using Failure Mode and Effects Analysis (FMEA) [8,9], leading to the definition of seven ISO-aligned improvement plans, each with predefined actions, indicators, and performance standards (Table 1) [10–13].

Within the ISO 9001:2015 framework, patient safety–focused indicators were predefined as key outcome and process measures, including ICU transfer rate, in-unit mortality, safety incident reporting rate, documentation completeness and quality, and equipment maintenance compliance, all derived from FMEA and aligned with ISO requirements for risk management and continuous improvement.

The ISO implementation process requires periodic internal and external evaluations. An internal audit was performed in October 2023 by the hospital's Quality Department identifying minor nonconformities and opportunities for improvement; the hospital management reviewed the implementation process and outcomes, with a satisfactory evaluation, and finally, an external audit in February 2024 granted ISO 9001:2015 certification. Since then, annual reassessments and a systematic follow-up of the predefined improvement plan indicators are carried out, comparing results against initial baseline values and optimal targets. This process enables continuous identification of improvement areas and corrective actions.

To evaluate the impact of the QMS, predefined and measurable activity and performance indicators derived from ISO 9001:2015 requirements were compared between the pre- and post-certification periods, allowing assessment of changes in

https://doi.org/10.1016/j.arbres.2026.01.005
0300-2896/© 2026 SEPAR. Published by Elsevier España, S.L.U. All rights are reserved, including those for text and data mining, AI training, and similar technologies.

**Table 1**
Summary of the IRCU quality improvement plans and key indicators.

| Plan (code) | Main action | Key indicators/standards |
|---|---|---|
| Talent development (OCAL-UCRI-2023-1) | Organization of regular training and clinical update sessions. | >80% of planned sessions completed; >55% attendance; annual satisfaction survey |
| Onboarding for new staff (OCAL-UCRI-2023-2) | Development of an initial training program tailored to new staff joining the unit. | 95% completion rate; 100% participation in knowledge survey |
| Documentation efficiency (OCAL-UCRI-2023-3) | Standardized digital admission/discharge forms; mandatory discharge reports (documentation quality was assessed through blinded internal audits based on eight mandatory items). | >95% completion rate; discharge report quality index >1.5 |
| Patient safety (OCAL-UCRI-2023-4) | A safety incident reporting protocol specific to the IRCU, adapted from CISE notification system, accompanied by awareness-raising actions. | Incident rate per 52,560 hours/year (24 h × 6 beds); IRCU incidents <50% of department total |
| Equipment maintenance (OCAL-UCRI-2023-5) | Inventory and periodic review of all unit equipment, with preventive maintenance scheduling, incident logging, and coordination with the hospital's maintenance contractor and suppliers. | >75% completion of scheduled maintenance (biannual review) |
| Patient & family satisfaction (OCAL-UCRI-2023-6) | QR-code survey in IRCU rooms linking to the unit's quality policy and an online satisfaction survey, alongside a suggestion box. | >80% 'high satisfaction' responses |
| Partner satisfaction (OCAL-UCRI-2023-7) | Joint meetings and surveys with key referring services (ICUs). | 80% meetings held; >75% positive responses |

*Abbreviations*: IRCU, Intermediate Respiratory Care Unit; CISE: Madrid Health Service; ICU, Intensive Care Unit.

**Table 2**
Predefined quality and performance indicators aligned with ISO 9001:2015 improvement plans in the Intermediate Respiratory Care Unit (IRCU), compared before and after certification.

| Objective/ISO domain | Indicator (definition) | 2023 (Pre-certification) | 2024 (Post-certification) | Relative change | Target/standard | *p* value |
|---|---|---|---|---|---|---|
| Activity/efficiency | Admissions, *n* | 131 | 235 | +79% | – | – |
| | Mean length of stay, days | 12.0 | 13.6 | +13.3% | – | – |
| | Patient complexity (mean DRG weight) | 1.980 | 1.710 | −13.6% | – | |
| Patient safety | ICU transfer rate, % | 28.2% | 3.0% | −89% | <10%[a] | <0.0001 |
| | Mortality rate, % | 16% | 4.7% | −70.6% | – | <0.05 |
| Continuous staff training | Training sessions completed, *n* | 12 | 20 | +66.7% | ≥80% planned sessions[a] | |
| | Staff attendance ≥1 session/month | – | >55% | | ≥55%[a] | |
| Integration of new personnel | Onboarding digital guide rating (0–5) | – | 4.8 | | — | |
| Documentation efficiency | Admission and discharge form completion, % | <90% | >90% | | >95%[a] | |
| | Discharge report quality index (0–2) | 1.41 | 1.86 | +32% | >1.5[a] | |
| Satisfaction | Patient and family satisfaction, (1–6) | 5.89 | 5.85 | −0.7% | 5.89 | |
| | Response rate (% of admissions) | 80% | 26% | −67.5% | 80% | |
| | Training staff satisfaction, (1–6) | 4.88 | 5.96 | +22.1% | – | |
| | Partner survey mean rating (1–6) | 4.73 | 5.62 | +18.8% | – | |

[a] Internal performance target defined during ISO 9001:2015 Quality Management System implementation.

clinical outcomes and efficiency parameters. All secondary objectives were operationalized through these indicators, each directly corresponding to a stated objective and enabling quantitative assessment of implementation-related progress and outcomes. Specific implementation plans and their associated indicators are detailed in the Methods section and summarized in Table 2, which presents each patient safety and quality indicator individually before and after certification, in accordance with ISO 9001:2015 requirements.

After ISO 9001:2015 implementation, predefined patient safety-focused indicators were evaluated individually as part of the quality management system.

Both mortality and ICU transfers decreased significantly during the implementation period. Mortality dropped from 16.0% to 4.7% ($\chi^2 = 12.19$, $p < 0.05$; OR 3.89, 95% CI: 1.81–8.35). ICU transfer rates also declined markedly, from 28.2% to 3.0% ($\chi^2 = 48.40$, $p < 0.0001$; OR 12.82, 95% CI: 5.52–29.78). These findings indicate statistically significant differences between periods within a descriptive before–after framework and should be interpreted in the context of the implementation-related changes described in this study.

A reduction in patient complexity was observed during the implementation period, reflected by a decrease in DRG weight from 1.980 to 1.710. Severity scores showed comparable baseline characteristics between cohorts (APACHE II 13.0 ± 2.5 vs 14.0 ± 1.8, $p = 0.782$; Charlson Index 1.37 ± 0.93 vs 1.73 ± 0.86, $p = 0.612$; SAPS-II 37.43 ± 1.8 vs 31.69 ± 2.3, $p = 0.896$).

Regarding specific objectives, the **Talent Development Plan** consolidated a continuous training program with 12 sessions in 2023 and 20 in 2024. All sessions were completed, and attended by more than 55% of staff. Satisfaction surveys (1 = not satisfied, 6 = very satisfied) revealed that 75% of responses in 2024 were in the highest categories, with a mean score of 5.96 versus 4.88 in 2023, and a participation rate of 95%.

**The Onboarding Plan** created an intranet-based digital guide with updated resources, schedules, and links to protocols, rated 4.8/5 by staff (response rate: 68%).

Under the **Documentation Efficiency Plan**, standardized admission and discharge forms were introduced. Completion rates exceeded 90%, and the discharge report quality index increased from 1.41 to 1.86 after audit-driven corrective actions. Documen-

tation completeness and quality were considered patient safety indicators due to their role in ensuring continuity of care and risk reduction.

The Patient Safety Plan introduced an IRCU-specific incident reporting system. In 2023, no independent registry existed, and nine incidents were recorded for the entire Department of Pneumology (rate: 0.000017 per patient-hour). After implementing the dedicated system in 2024, incidents increased numerically; however, this was interpreted as improved detection and more accurate reporting rather than an increase in adverse events. Specifically, IRCU-related incidents accounted for 37% of the department's total (rate: 0.000057), remaining within the predefined threshold (<50%). This indicator was therefore interpreted as reflecting enhanced monitoring of safety events rather than a deterioration in patient safety.

The **Equipment Maintenance Improvement Plan** included an updated inventory of critical devices—ventilators, high-flow systems, capnographs, monitors, and ultrasound—together with scheduled preventive maintenance coordinated with technical services and suppliers. In 2023, 252 maintenance issues were recorded across the Pneumology Department; after implementation in 2024, IRCU-specific incidents decreased to 98, achieving 80% compliance and surpassing the established target. This indicator was directly linked to patient safety through the prevention of device-related adverse events.

The **Patient and Family Satisfaction Plan** maintained excellent results throughout the study. In late 2023, patients and relatives rated IRCU care at 5.89/6 ($n = 11$, 80% of admissions), and in 2024 scores remained high at 5.85/6 ($n = 55$, 26% of total admissions). The **Partner Satisfaction Plan** assessed perceptions among physicians from continuity-of-care services (medical and surgical ICUs). In 2023, the mean rating was 4.73/6 ($n = 11$, 30% response rate); in 2024, participation increased ($n = 16$, 40%) with higher satisfaction levels (5.62/6).

To our knowledge, this is the first systematic description of the implementation and certification of ISO 9001:2015 in an IRCU. This highlights both the emerging role of IRCUs and the lack of organizational standardization in such facilities. In our experience, ISO 9001:2015 implementation allowed the unit to systematize its processes, assign clear responsibilities, and establish a culture of continuous evaluation. This reorganization fostered greater engagement among healthcare staff and was associated with improvements in efficiency and selected clinical outcomes. Specifically, we observed a marked reduction in ICU transfers and mortality rates during the certification period, which should be interpreted within the context of organizational and process-related changes associated with the implementation of the ISO 9001:2015 Quality Management System, rather than as evidence of direct causal effects. These outcomes are likely linked to improved staff training, standardized admission criteria, homogenization of procedures and discharge reports, and the implementation of safety protocols.

Similar experiences have been reported in other areas: Betlloch-Mas et al. [14] described system reorganization and improved compliance after ISO implementation in a dermatology unit; Torrent et al. [15] documented its feasibility in ICUs; and subsequent studies showed improved protocol adherence from 62% to 85% ($p < 0.01$) post-certification [16]. In home hospitalization units, certification reduced readmissions and increased satisfaction [17]. A European multicenter analysis [18] linked ISO 9001 certification to better patient safety strategies, particularly in neurology and stroke units, while Hungarian hospitals with certification scored higher in quality and human resource management [19]. Recent evidence also highlights its role in reducing communication errors and improving traceability in vascular care [20].

Certification also reinforced the IRCU's identity as a differentiated care unit within the hospital, enhancing predictability, traceability, and transparency in management. Furthermore, it improved coordination with other departments through periodic surveys, which should be expanded to include additional services (e.g., Emergency Department) and staff categories (e.g., nursing, auxiliary staff).

A particularly relevant achievement was the creation of patient safety-focused indicators, which improved early detection of incidents and implementation of preventive measures. A key added value of the ISO 9001:2015 implementation was the formal definition of these indicators, each linked to a specific risk domain and monitored through predefined standards. Reporting them individually allowed targeted corrective actions and facilitated the development of a practical self-assessment framework applicable to other IRCUs.

This is consistent with previously reported evidence [15,17], emphasizing the role of certification in structuring processes and monitoring clinical risks.

An important consideration when interpreting our findings is the observed reduction in case complexity during 2024, reflected in the decrease in DRG weight. Although severity scales were comparable, admission criteria became more restrictive—considering frailty, comorbidity, reversibility of acute illness, and excluding multiorgan failure—resulting in a more homogeneous patient population. Therefore, while improvements in outcomes are robust, the contribution of reduced complexity versus process standardization cannot be fully disentangled.

This study was conceived as an implementation and feasibility evaluation of a quality management system rather than as a controlled outcome study, and therefore causal interpretation of the observed changes is limited. Several additional limitations must also be considered: This observational pre–post study without a control group precludes causal inference; observed improvements may reflect Hawthorne effects, natural maturation of the unit, or concurrent organizational changes rather than the ISO certification itself. Patient complexity decreased during the implementation period, as indicated by the reduction in mean DRG weight, which may have acted as a confounder. Although baseline severity scores were comparable, the absence of comprehensive severity adjustment (e.g., SAPS-3) limits disentanglement of case-mix effects from process standardization. The relatively short post-certification follow-up (one year) restricts assessment of long-term sustainability. Low response rates in satisfaction surveys (26% patients; 40% partners) may introduce selection bias; the decrease compared with earlier phases likely reflects reduced reminders as workflows became routine, and non-responder analysis was not feasible due to survey anonymity. Additionally, some pre-certification activity data were unavailable, the transversal structure of the IRCU limits its evaluation using conventional departmental indicators, and the lack of other ISO-certified IRCUs precludes external benchmarking and limits generalizability. Certification-related costs were not formally analyzed; although cost-effectiveness was not evaluated, it is reasonable to assume that avoiding ICU transfers may yield substantial indirect economic benefits, given the markedly higher costs of ICU admissions. Together, these limitations highlight the need for standardized indicators, clearer regulatory frameworks, and multicenter evaluations.

Based on our experience, ISO 9001:2015 certification is a useful and adaptable tool for structuring and evaluating emerging clinical units such as IRCUs. Its success relies on leadership, multidisciplinary involvement, and systematic indicator-based monitoring. The model described may serve as a reference for other units seeking to enhance organizational and clinical quality through internationally recognized standards.

Future priorities include developing standardized IRCU indicators, assessing certification's impact on patient experience and costs, and promoting their formal recognition as strategic care units within hospital systems.

In conclusion, implementation of the ISO 9001:2015 Quality Management System was associated with improvements in organizational structure, patient safety processes, documentation quality, and selected clinical and efficiency indicators, while fostering a lasting culture of evaluation, teamwork, and continuous improvement across the unit and the institution.

## Author contributions

All authors contributed substantially to the conception and design of the study, data acquisition, analysis, and interpretation. All authors participated in drafting and revising the manuscript, approved the final version, and agree to be accountable for all aspects of the work.

## Ethical considerations

The study was conducted in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments. The project was reviewed and approved by the Ethics Committee of Hospital Universitario Puerta de Hierro–Majadahonda.

## Informed consent

This study did not involve individual patient data or interventions; therefore, informed consent was not required.

## Use of artificial intelligence

Artificial intelligence was used exclusively for language translation and editing of the English version of the manuscript. All data analysis, interpretation, and conclusions were performed by the authors.

## Funding

No funding was received for this study.

## Conflicts of interest

The authors declare that they have no conflicts of interest.

## References

[1] Cammarota G, Esposito T, Azzolina D, et al. Noninvasive respiratory support outside the intensive care unit for acute respiratory failure related to coronavirus-19 disease: a systematic review and meta-analysis. Crit Care 2021;25:268.
[2] International Organization for Standardization. ISO 9001:2015 quality management systems—requirements. Geneva: ISO; 2015. Available from: https://www.iso.org/standard/62085.html
[3] European Foundation for Quality Management. Available from: https://efqm.org/es/.
[4] European Foundation for Quality Management. EFQM Model 2020. Brussels: EFQM; 2020.
[5] Joint Commission on Accreditation of Healthcare Organizations. Available from: http://www.jointcommission.org/.
[6] Heidari S, Tavakkoli-Moghaddam R, Salimi B, Mehdizadeh-Somarin Z, Hamid M. An integrated approach for evaluating and improving the performance of hospital ICUs based on ergonomic and work-motivational factors. Comput Biol Med 2024;168:107773.
[7] Akduman S, Yilmaz K. Examining the effectiveness of artificial intelligence applications in asthma and COPD outpatient support in terms of patient health and public cost: SWOT analysis. Medicine (Baltimore) 2024;103:e38998.
[8] Liu HC, Zhang LJ, Ping YJ, Wang L. Failure mode and effects analysis for proactive healthcare risk evaluation: a systematic literature review. J Eval Clin Pract 2020;26:1320–37.
[9] Ullah E, Baig MM, GholamHosseini H, Lu J. Failure mode and effect analysis (FMEA) to identify and mitigate failures in a hospital rapid response system (RRS). Heliyon 2022;8:e08944.
[10] Charlson ME, Carrozzino D, Guidi J, Patierno C. Charlson Comorbidity Index: a critical review of clinimetric properties. Psychother Psychosom 2022;91:8–35.
[11] Jahn M, Rekowski J, Gerken G, Kribben A, Canbay A, Katsounas A. The predictive performance of SAPS 2 and SAPS 3 in an intermediate care unit for internal medicine at a German university transplant center: a retrospective analysis. PLOS ONE 2019;14:e0222164.
[12] Duan J, Chen L, Liu X, et al. An updated HACOR score for predicting the failure of noninvasive ventilation: a multicenter prospective observational study. Crit Care 2022;26:196.
[13] Colussi G, Botto A, Giudicessi R, et al. Evaluating quality of electronic clinical notes using the Spanish version of Physician Documentation Quality Instrument (PDQI-9) in a high-complexity hospital: cross-sectional study. Stud Health Technol Inform 2020;270:587–91.
[14] Betlloch-Mas I, Ramón-Sapena R, Abellán-García C, Pascual-Ramírez JC. Implementation and operation of an integrated quality management system in accordance with ISO 9001:2015 in a dermatology department. Actas Dermosifiliogr (Engl Ed) 2019;110.
[15] Lorenzo Torrent R, Sánchez Palacios M, Santana Cabrera L, et al. Management of quality in an intensive care unit: implementation of ISO 9001:2008 international standard. Med Intensiva 2010;34:476–82.
[16] Karampela I, Tzortzis E, Nikolopoulos M, et al. A hospital information system application may facilitate staff compliance with quality protocols in a medical unit: a case study. Stud Health Technol Inform 2018;251:203–6.
[17] Rodríguez-Cerrillo M, Fernández-Diaz E, Iñurrieta-Romero A, Poza-Montoro A. Implementation of a quality management system according to ISO 9001 standard in a hospital-at-home unit: changes and achievements. Int J Health Care Qual Assur 2012;25:498–508.
[18] Shaw CD, Groene O, Botje D, et al. The effect of certification and accreditation on quality management in 4 clinical services in 73 European hospitals. Int J Qual Health Care 2014;26 suppl 1:100–7.
[19] Dombrádi V, Csenteri OK, Sándor J, Godény S. Association between the application of ISO 9001:2008 alone or in combination with health-specific standards and quality-related activities in Hungarian hospitals. Int J Qual Health Care 2017;29:283–9.
[20] Avruscio G, Ragazzo S, Ceccato D, et al. Implementation of a quality management system according to ISO 9001:2015 standards in an angiology unit: an Italian experience. Ann Ig 2022;34:627–34.

Silvia Aguado Ibáñez [a,*], Beatriz Jara Chinarro [a], Ainhoa Izquierdo Pérez [a], Manuel Valle Falcones [a], María Dolors Montserrat Capella [b], Ernesto Gómez Cubillo [a], Antonia Cachinero Murillo [a], Carlos Almonacid Sánchez [a], on behalf of the Quality and Training Group of the Intermediate Respiratory Care Unit, Department of Pulmonology, Hospital Universitario Puerta de Hierro–Majadahonda

[a] *Department of Pulmonology, Hospital Universitario Puerta de Hierro–Majadahonda, Madrid, Spain*
[b] *Quality Management Department, Hospital Universitario Puerta de Hierro–Majadahonda, Madrid, Spain*

*Corresponding author.
*E-mail address:* s.aguado.ibanez@gmail.com (S. Aguado Ibáñez).