Original Article

Quality Assessment of the Iran Intensive Care Unit Registry: A Validation Evaluation Using International Medical Registry Frameworks (2017–2024)

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What's Known

- High-quality national intensive care unit (ICU) registries are essential for benchmarking, outcome monitoring, and quality improvement. However, most low- and middle-income countries lack comprehensive ICU data systems.
- Standardized frameworks (DoCDat, Arts et al., ANZICS) have been successfully used internationally to assess registry structure and data quality.

What's New

- This study reported the development and first nationwide implementation of the Iran intensive care unit registry (IICUR), enabling multicenter data collection from 39 ICUs across 16 hospitals.
- For the first time, the methodological quality, representativeness, and data completeness of IICUR were rigorously validated using internationally accepted scoring frameworks.

Abstract

Background: The Iran intensive care unit registry (IICUR) was established to systematically collect high-quality clinical data from critically ill adult patients nationwide. This registry was created to fill a major gap in Iran by providing the first coordinated national intensive care unit (ICU) data system to support benchmarking, quality improvement, and research. This study aimed to assess the registry's data quality, representativeness, and performance using internationally recognized evaluation frameworks.

Methods: This validation study included consecutive adult ICU admissions (aged≥16 years) recorded in the IICUR between October 2017 and October 2024 across 39 ICUs in 16 hospitals in Shiraz, Iran. Data quality was assessed based on the directory of clinical databases (DoCDat) and Arts et al., frameworks. Evaluated domains included case representativeness, variable completeness, data validation processes, and coding reliability. Statistical analyses were performed using SPSS software (version 24).

Results: Overall, 34,550 ICU admissions were registered (36% surgical, 64% medical). The patient's mean age was 49.4 years, with an average ICU stay of 6.7 days. The registry achieved a median DoCDat score of 3.0 (on a 1–4 scale), indicating strong national coverage, standardized data definitions, and high recruitment completeness. Trauma, neurological, and respiratory disorders were the most common admission causes. ICU and hospital mortality rates were 13.8% and 16.4%, respectively. Despite its strengths, enhanced data validation and post-discharge follow-up were required.

Conclusion: The IICUR demonstrated high methodological standards, providing a robust national platform for benchmarking, policy development, and critical care research in Iran.

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Introduction

Intensive care units (ICUs) provide specialized care for critically ill or injured patients who require continuous monitoring and advanced organ support.[1] These patients often exhibit complex physiological abnormalities that generate high-resolution clinical

data essential for diagnosis, management, and outcome prediction.[2, 3] The systematic capture of such data in high-quality clinical databases is fundamental for advancing healthcare delivery, guiding policy, optimizing resource allocation, and fostering clinical research in critical care medicine.[4]

Clinical quality registries (CQRs) serve as core instruments within modern healthcare systems by enabling standardized data collection and outcome benchmarking across institutions.[5] Over the past 2 decades, large-scale ICU registries such as the Australian and New Zealand intensive care society (ANZICS) Adult Patient Database,[6] the UK's intensive care national audit and research center (ICNARC), and the Dutch national intensive care evaluation (NICE) have demonstrated how continuous data-driven evaluation can directly improve quality of care, reduce variation, and enhance patient outcomes.[7, 8] More recently, digital infrastructure and interoperability frameworks have further strengthened the clinical and research capabilities of national registries, as highlighted in the 2024 Australian framework for national clinical quality registries.[9]

While high-income countries have benefited substantially from integrating national ICU registries, low- and middle-income countries (LMICs) continue to face significant challenges in developing such platforms, despite their higher burden of critical illness and healthcare disparities.[10] Global collaborative initiatives such as the Critical Care Asia Network and the World Federation of Societies of Intensive and Critical Care Medicine registry consortiums emphasize that well-structured LMIC registries can substantially improve transparency, performance measurement, and scientific contributions when supported by robust governance and sustainable informatics systems.[11, 12]

The Iran intensive care unit registry (IICUR) was established to address the absence of national-level ICU data systems and to promote quality improvement through evidence-based benchmarking. Evolving from the earlier Shiraz intensive care unit registry (SICUR), IICUR aims to systematically record high-quality, standardized data from adult ICU admissions nationwide. Its design and quality assurance structure follow internationally validated frameworks, including the DoCDat and the Arts et al., model, to ensure data completeness, representativeness, and reliability.[13, 14] This study evaluated the quality of the IICUR data using established criteria and provided an overview of the characteristics and outcomes of patients admitted between 2017 and 2024. The previously published ANZICS registry established these methodological benchmarks;[15] the present study evaluated the IICUR using these published frameworks for the first time in Iran.

Materials and Methods

Study Design and Setting

This study was designed as a validation study to investigate the quality of the data on consecutive adult ICU admissions (aged ≥16 years) between October 2017 and October 2024, in Shiraz, Iran. These data were collected from standardized medical records and hospital information systems across multiple centers in Iran. Historical data were extracted and analyzed to assess registry data quality, representativeness, and performance according to established evaluation criteria. The registry includes 39 ICU wards across 16 hospitals from various regions of Iran. Its design was based on internationally accepted frameworks for developing and evaluating clinical registries, particularly the DoCDat and the Arts et al., quality assurance model.[14]

Framework and Development

The registry was developed under the coordination of Shiraz Anesthesiology And Critical Care Research Center (SACRC). Initial collaboration began with the ANZICS Centre for outcome and resource evaluation (CORE) in 2016.[6, 15] A local pilot database was first implemented at Namazi Hospital (Shiraz, Iran), which later evolved into the SICUR. This network progressively expanded to become IICUR, integrating additional ICUs in Tehran, Rasht, Gonabad, and other cities as recognized by the Ministry of Health and Medical Education of Iran. The registry infrastructure aligns with the good clinical quality registry practice guide, emphasizing harmonized governance, standardized data dictionary construction, and continuous system monitoring.[16]

Data Collection Procedures

All adult ICU admissions at participating centers were enrolled without exclusions, unless data completeness was compromised. Data collection was conducted using standardized forms containing 129 variables covering demographics, admission details, diagnosis, interventions, outcomes, and physiological measures such as the acute physiology and chronic health evaluation II (APACHE II) score. During 2018-2021, iterative updates were made to adapt the data dictionary to local needs, including replacing race with immigration status

and adding variables for substance abuse and pandemic-related outcomes. During the COVID-19 pandemic, a supplementary 35-item questionnaire was appended to record COVID-specific parameters, such as ventilatory support type, antiviral use, and infection confirmation method.

Data Collection Tools and Software

Data were first recorded on standardized paper forms and subsequently entered into bespoke electronic registry software derived from the ANZICS COMET system. The software was localized under ANZICS supervision and introduced Persian-language user interfaces and customized data export functions. Regular user feedback informed iterative updates, ensuring user-friendliness and compliance with registry quality standards described in the 2024 Australian clinical quality registry framework.[16] Built-in quality control functions allowed real-time range and plausibility checks. Each registry site was assigned a trained data manager, and local site coordinators conducted weekly meetings with the IICUR central team for process optimization. Core members, including clinicians, epidemiologists, informaticians, and statisticians, supervised training sessions, contributing to inter-observer consistency and standardization.

Data Ownership, Privacy, and Ethics

Patient data collected from participating public and teaching hospitals are jointly governed by the Ministry of Health and Medical Education, with institutional agreements defining access and use. Data anonymization and encryption were applied before storage and analysis. Only approved researchers were granted de-identified datasets for analysis, following authorization from the corresponding academic institutions. The registry adheres to national data protection regulations and global standards for medical registries.[17] Paper-based forms were securely stored at each center and accessed only for resolving discrepancies during electronic data verification. This retrospective study was approved by the Ethics Committee of Shiraz University of Medical Sciences (code: IR.SUMS.REC.1402.132). Informed consent requirements were waived due to the use of de-identified secondary data.

Funding and Independence

The IICUR is supported by Shiraz University of Medical Sciences, alongside monitored private donations. All funding sources function under strict non-interference agreements regarding data collection, analysis, and dissemination to ensure research independence.

Data Quality and Evaluation

Data quality was assessed using the DoCDat criteria and the Arts et al., framework. Two external evaluators and IICUR core members independently scored the registry's performance across all DoCDat domains, including representativeness, data completeness, validation, and coding reliability. Central and local site procedures followed three hierarchical categories: (a) prevention of data quality issues, (b) detection of inconsistencies, and (c) corrective actions.[14, 18] Ongoing periodic audits, range and consistency tests, and regular updates to variable definitions were maintained to ensure compliance with good registry practice guidelines.[16, 19] Each of the 10 DoCDat criteria was independently scored on a 1-4 point scale by four core members of the IICUR team and three external evaluators. The final score for each domain was calculated as the median value of all raters' assessments to minimize the influence of outliers. The total DoCDat score was derived as the average of these 10 median domain scores (Appendix table A).

Results

Registry Coverage and Enrollment

Since its establishment, the IICUR has expanded to include 39 ICU wards across 16 hospitals, encompassing a total of 308 active ICU beds. Between October 2016 and October 2024, the registry documented 34,550 ICU admissions, representing a balanced cohort of 36% surgical and 64% medical patients. This broad inclusion ensured the representativeness of the IICUR population for national-level benchmarking and epidemiologic evaluations.

Quality Assessment based on DoCDat

The overall median total score for IICUR quality, evaluated against the DoCDat criteria, was 3.0 (on a 1–4 scale), suggesting strong national-level representativeness, high-definition variable clarity, and consistent recruitment across centers. A detailed comparison between IICUR and DoCDat benchmark databases demonstrates acceptable performance across all domains (table 1). The registry achieved notably high ratings in variable definition (level 4), explicit recording rules (level 4), and completeness of data (levels 3-4).

The registry demonstrated a high level of national representativeness (level 3), evolving from a single ICU in 2016 to a comprehensive, nationwide platform by 2023.

Table 1: Performance of the IICUR based on the DoCDat evaluation criteria

Variable	IICUR	DoCDat database
Representativeness of country	3 (2-3)	3 (2-4)
Completeness of recruitment	3 (2-3)	3 (1-4)
Variables included	3 (3-3)	3 (2-4)
Completeness of data	3 (3-4)	2 (1-3)
Data collection format	3 (3-4)	4 (4-4)
Explicit definitions	4 (4-4)	2 (1-4)
Explicit rules	4 (3-4)	2.5 (1-4)
Reliability of coding	3 (3-4)	1 (1-4)
Independence of observations	3 (2-3)	4 (2-4)
Data validation	2 (2-2)	3 (3-4)
Total	3 (3-4)	3 (2-4)

The values are indicated Median (Q_1-Q_3); IICUR: Iran intensive care unit registry; DoCDat: Directory of clinical databases

During that year alone, it documented 11,149 ICU admissions across multiple provinces, reflecting extensive geographic and institutional diversity. Recruitment completeness (level 3) was also robust, as nearly all eligible adult ICU patients were enrolled, with data collected concurrently with routine clinical care activities, thereby minimizing the likelihood of missed cases.

The scope of variables included in the registry (level 3) was broad, encompassing key demographic and clinical domains, such as admission source, primary diagnosis, invasive and non-invasive interventions, outcomes, and validated severity indices, notably the APACHE II and frailty scores. Although long-term post-discharge outcomes are not yet incorporated, their systematic collection is being developed to enhance longitudinal surveillance and quality improvement initiatives.

Data completeness (level 3) was maintained through a two-step acquisition process comprising initial paper-based documentation followed by centralized electronic verification. This dual approach effectively minimized transcription errors and ensured high data integrity. The data collection format (level 3) adhered to strict procedural consistency, with all variables recorded in their original raw form and standardized for measurement units to facilitate cross-center comparability.

Explicit definitions and coding reliability (levels 4 and 3) were continually reinforced through iterative review sessions and adherence to structured codebooks, which ensured semantic consistency and improved interoperability among participating centers. Independence of observation (level 3) was largely preserved in tertiary hospitals where trained registry staff, independent of direct patient care, were responsible for data entry. However, in smaller community hospitals, some data were entered by dual-role clinical personnel, which might have slightly lower observational independence.

Finally, the registry's data validation performance (level 2) reflected ongoing development. Automated range and logic consistency checks were routinely executed at the time of data entry, while full external validation audits and inter-observer reliability assessments remained under implementation as part of the registry's continuous quality improvement agenda.

Quality Assessment based on Arts et al., Framework

Using the Arts et al., framework for registry evaluation, IICUR fulfilled nearly all central coordinating criteria except for seven items, including automated consistency auditing and formal inter-observer variability assessments. Conversely, most local sites successfully met 10 key quality procedure components, indicating effective decentralized data governance (Appendix table B).

Registry Trends and Patient Characteristics

Enrollment increased from 107 patients in 2016 to 11,149 in 2023, signifying successful registry scaling. Across all years, the mean age of patients was 49.35±21.03 years, and the mean ICU length of stay was 157.68±214.08 hours (approximately 6.7 days). The median APACHE II score was 14 (IQR: 9-21).

Over the study period, the annual number of ICU admissions increased significantly, reflecting progressive expansion and maturation of the registry network (table 2, figure 1).

Across calendar years, the case mix shifted from a predominantly surgical to a more balanced or medical-dominant population, indicating diversification of participating ICUs and improved capture of medical cases (table 2).

Outcomes and Mortality

The overall ICU mortality rate during the study period was 13.8%, while the overall hospital mortality reached 16.4%. Among all admissions, 86.2% of patients were discharged alive.

Table 2: Annual ICU admissions, diagnostic categories, and mortality trends in the IICUR (2016–2024)

	2016 (Oct) Started in ANZICS n=107	2017 (Oct) Started in IICUR n=386	2018 n=646	2019 n=1,963	2020 n=1,774	2021 n=3,006	2022 n=7,518	2023 n=11,149	2024 (Oct) n=8,001	Total n=34,550
Surgical	67.9	61.8	22.8	48.8	54.3	49.7	41.6	37.4	36.1	46.7
Medical	32.1	38.2	77.2	51.2	45.7	50.3	58.4	62.6	63.9	53.3
ICU mortality	11.3	12.4	14.6	11.9	15.1	14.04	14.6	15.1	15.1	13.8
Hospital mortality	12.8	14.2	16.5	17.3	16.2	19.1	17.0	16.8	17.4	16.4

Values are shown as percentages. ICU: Intensive care unit; ANZICS: Australian and New Zealand intensive care society; IICUR: Iran intensive care unit registry

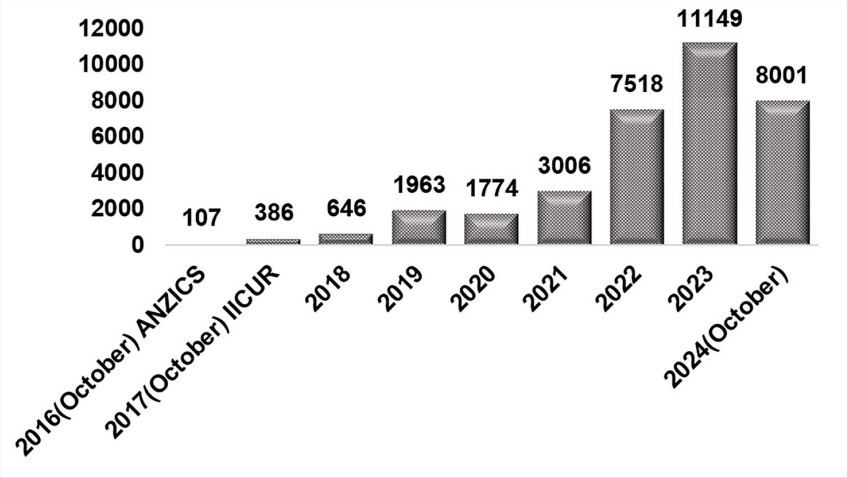


Figure 1: This figure shows the annual number of ICU admissions recorded in the IICUR from 2016 to 2024, illustrating the progressive growth of the registry and the increase in enrolled cases over time. ANZICS: Australian and New Zealand intensive care society; IICUR: Iran intensive care unit registry

The majority were transferred to regular wards (69.7%), while 9.1% were discharged home directly, and 2.5% were transferred to another hospital (table 3).

Admission Sources and Diagnostic Patterns

Admissions from the Emergency Department accounted for 50.4% of total cases, followed by operating room/recovery admissions (33.6%), confirming a balanced integration between medical and surgical populations (figure 2).

Trauma remained the leading cause of ICU admission (11,593 cases), of which 25.3% required surgery. Neurological (6,870 cases) and respiratory (4,256 cases) disorders were the next most frequent diagnostic categories (figure 3). The top three specific causes of ICU admission were multiple traumas, head trauma, and drug overdose, accounting for 20.7%, 8.1%, and 5.7% of total admissions, respectively.

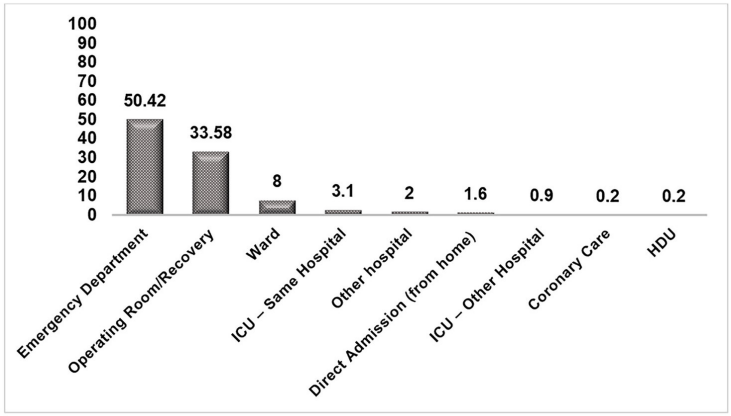
Comorbidities and Interventions

Diabetes mellitus and cardiovascular diseases were the two most prevalent preexisting conditions (19.4% and 15.3%, respectively; table 4). Intervention data indicated that 46.5% of patients required invasive mechanical ventilation, with a mean ventilation duration of 64.6 hours, while 13.5% underwent non-invasive ventilation for a mean duration of 38.6 hours (table 5).

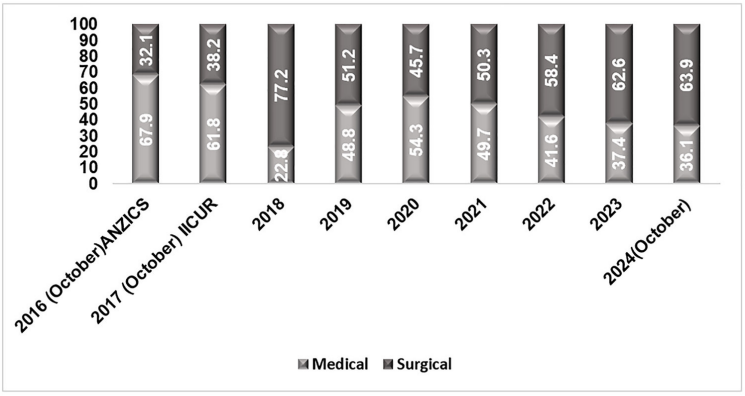
Table 3: Outcomes of patients admitted to ICUs participating in the IICUR registry

Transferred to ward	69.7
Transferred to another ICU	4.9
Transferred to another hospital	2.5
Transferred directly to home	9.1
Mortality	13.8
ICU LOS	Mortality
<7 days	57.7
7-14 days	21.3
>14 days	21

Values are shown as percentages. LOS: Length of stay; ICU: Intensive care unit; IICUR: Iran intensive care unit registry

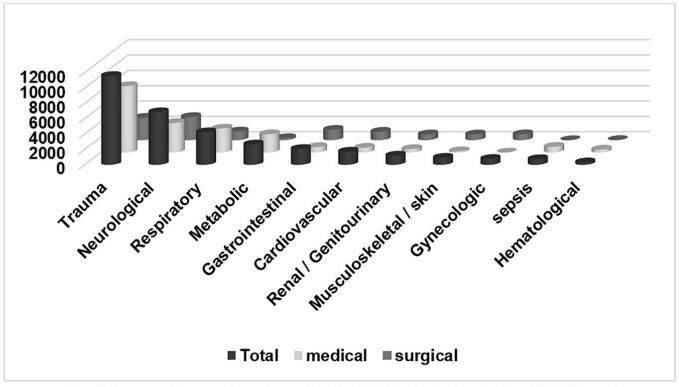


(A) Proportion of ICU admission sources in the IICUR registry

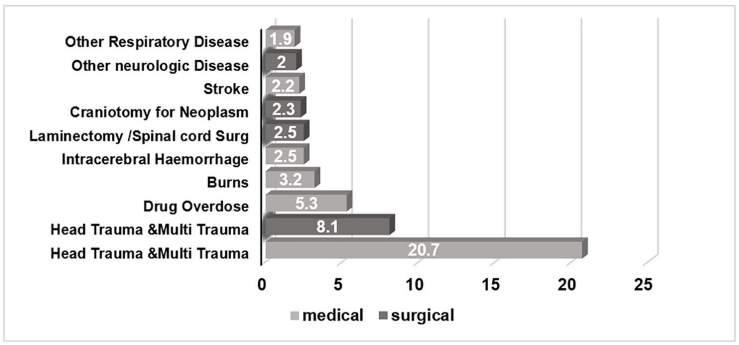


(B) Annual distribution of medical and surgical ICU admissions in the IICUR registry

Figure 2: A: The figure depicts the distribution of ICU admission sources in the registry, including admissions from the emergency department, operating room/recovery, and other hospital locations. B: It demonstrates the annual proportions of medical versus surgical ICU admissions across the study period. ANZICS: Australian and New Zealand intensive care society; IICUR: Iran intensive care unit registry; ICU: Intensive care unit



(A) Primary diagnostic categories for ICU admission in the IICUR registry



(B) Most common specific conditions leading to ICU admission in the IICUR registry

Figure 3: This figure presents the primary diagnostic categories leading to ICU admission in the IICUR and displays the ten most frequent specific conditions. IICUR: Iran intensive care unit registry; ICU: Intensive care unit

Table 4: Prevalence of chronic comorbid conditions among ICU patients in the IICUR registry	
Diabetes mellitus	19.4
Chronic cardiovascular	15.3
Immune disease	9.5
Chronic respiratory disease	6.7
Immunosuppression	3.5
Chronic renal failure	2.9
Metastatic lesion	2.3
Cirrhosis (biopsy proven)	0.6
Hepatic failure	0.4
Lymphoma	0.2
Leukemia/myeloma	0.2
AIDS	0.1

Values are shown as percentages. AIDS: Acquired immunodeficiency syndrome; IICUR: Iran intensive care unit registry

Table 5: Interventions and supportive treatments administered to ICU patients in the IICUR registry	
Invasive ventilation	46.47%
Mean duration (hours)	64.58
Non-invasive ventilation	13.52%
Mean duration (hours)	38.65
Need for vasopressors	15.39%
Tracheostomy	7.59%
Renal replacement therapy	3.97%
ECMO	0.03%

ECMO: Extracorporeal membrane oxygenation; IICUR: Iran intensive care unit registry

Table 6: Distribution of frailty scores among patients registered in the IICUR (2017-2024)	
Very fit	1.26
Well	25.9
Managing well	23.1
Very mild	19.9
Mild	12
Moderate	11.4
Severe	5.69
Very severe	0.74
Terminally ill	0

Values are shown as percentages. IICUR: Iran intensive care unit registry

Detailed other reasons, including neurological and respiratory diseases, were provided in the Appendix table C.

Frailty scoring was assessed for all registered patients, and its distribution is summarized in table 6. The largest proportions of ICU admissions were classified as “Well” (25.9%) and “Managing well” (23.1%). None of the patients was categorized as terminally ill at the time of ICU admission. This distribution indicates that the majority of ICU patients in the IICUR had mild to moderate frailty statuses, with a relatively small proportion demonstrating advanced frailty levels.

Discussion

The present study provided the first comprehensive assessment of the data quality, structure, and representativeness of the IICUR, spanning nearly a decade of national development. Originating from the SICUR, this platform evolved into Iran’s first nationwide critical care database, constructed according to the DoCDat and Arts et al., frameworks. It demonstrated that scalable ICU registries could be successfully implemented in middle-income settings through structured governance, standardized data dictionaries, and continuous training, similar to the experiences of the PRICE registry in Pakistan and the Crit Care Asia (CCA) network.[5, 20]

In addition to the Pakistan PRICE initiative and the Crit Care Asia network, recent data from other Middle Eastern and neighboring countries demonstrated that structured critical care databases and multicenter quality initiatives are increasingly being established across the region. For example, national and multicenter efforts from Turkey[21] and Gulf states[22] reported

on ICU organization, bed capacity, case mix, and outcomes, highlighting similar challenges in infrastructure, staffing, and standardization of data collection.

These reports collectively indicated that many middle-income health systems in the broader Middle East are in a transitional phase, moving from fragmented, hospital-based ICU data toward more coordinated registry models, with variable degrees of national coverage and methodological rigor. Within this evolving landscape, the IICU Registry provides one of the first examples of a national, methodologically evaluated ICU registry in the region, aligned with international frameworks (DoCDat and Arts et al.), and thus contributes a critical piece of infrastructure for benchmarking and regional collaboration in critical care quality improvement.[21]

The overall DoCDat performance score of 3.0 indicated a well-structured registry with strong representativeness, completeness, and clarity of variable definitions. The system evolved from a single ICU in 2016 to 16 hospitals by 2024, mirroring growth models achieved by the ANZICS CORE network and the Epimed Monitor registry, both of which emphasize phased expansion and rigorous standardization.[11, 23] By collecting comprehensive variables across demographics, interventions, and outcomes, IICUR aligns with international standards such as NICE, ICNARC, and Epimed, enabling valid benchmarking across systems.[8] The registry's design principles ensure interoperability and provide a foundation for longitudinal health policy analysis in critical care.

The predominance of trauma and neurological cases reflects regional disease burden trends common in low- and middle-income countries, consistent with Sub-Saharan and South Asian registries.[24] The overall ICU mortality rate (13.8%) was in agreement with findings from the Epimed and CCA datasets, which reported mortality rates between 13% to 19% in comparable populations.[20, 25] The observed predominance of emergency admissions underlined the need for improved prehospital care integration, a challenge similarly documented across the PRICE and JIPAD registries.[4, 26]

The hybrid data entry approach—paper-based collection followed by centralized electronic validation—proves particularly effective in diverse infrastructure environments. Similar models were highlighted in global reviews emphasizing flexible, resource-adaptive registry architectures.[19] The system's adherence to the Arts et al., quality framework and the Good Clinical Quality Registry Practice Guide (2025) promoted sustained integrity across centers.[16]

The registry currently lacks full-cycle external validation procedures and inter-observer reliability testing—components that could enhance longitudinal accuracy. Similar transitional gaps were reported in the Danish ICU database during its early implementation.[8] To advance data verification, automated cross-validation models and AI-driven audit algorithms, already piloted in modern registry pipelines, should be integrated.[27] The integration of long-term outcomes, including post-ICU quality of life, readmission data, and mortality tracking, remains an essential next phase. This follows the global paradigm shift from episode-based metrics toward continuum-of-care surveillance, as reflected in Epimed 2024, the European Registry of Intensive Care, and Post-ICU Follow-Up Initiatives.[28]

Beyond clinical insight, IICUR provides vital infrastructure for policy formulation, resource allocation, and regional benchmarking. National-level registry integration fosters transparency, enhances capacity building, and facilitates provincial data collaboration, as observed in the Epimed Network, CCA, and ICNARC systems.[11, 26]

This study's strengths included its national scope, methodological rigor, and external evaluation framework application. However, heterogeneity in data entry independence and the current absence of automated critical checks represented limitations associated with growing registries. These issues could be mitigated by integrating real-time digital validation and secure hospital interoperability systems, a strategy prioritized in next-generation e-registry deployments.[17] The development and expansion of the IICUR were constrained by restricted funding, heterogeneous IT infrastructure, and incomplete integration with electronic medical record systems, which restricted the uniform implementation of advanced validation tools and external audits. In addition, variability in ICU staffing, informatics capacity, and broader macroeconomic pressures within Iran's healthcare system might contribute to the differences in data completeness and quality across centers and should be considered when interpreting the registry's performance metrics.

Conclusion

The IICUR demonstrated that structured national critical care data systems could be established and sustained in low-resource environments. Its adherence to international standards, consistent data completeness, and multicenter coverage affirmed its reliability as an emerging regional

model. Future integration of post-discharge follow-up, automated validation, and machine learning-based analytics will further position IICUR as a catalyst for clinical research, guideline evaluation, and quality improvement within Iran and worldwide.

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Author's Contribution

F.Z: Conceptualization, study design, and drafting; G.S: Conceptualization, study design, and drafting; N.A: Study design, data analysis, drafting and reviewing the manuscript; M.N: Study design, data gathering, and drafting; H.S: Study design, data gathering, and drafting; S.S: Conceptualization, and drafting; A.F: Conceptualization, and drafting; M.B: Conceptualization, data interpretation, and reviewing the manuscript; F.A: Conceptualization, data gathering, data interpretation and reviewing the manuscript; All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

AI Declaration

As the authors are not native speakers of English, Grammarly's AI-based language editing tool was used to improve the clarity and grammar of the manuscript.

Conflict of Interest

Farid Zand, serving as the Editor-in-Chief, and Naeimehossadat Asmarian, serving as an Editorial Board Member of the Journal, played no role in the handling of this manuscript at any stage. To ensure impartiality, the Editorial Board convened a team of independent experts to review the manuscript without their involvement or awareness.

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