

# HumanITA-ICUs: humanizing Italian intensive care units. A survey study protocol

## HumanITA-ICUs: umanizzare le unità di terapia intensiva italiane. Surevey Study Protocol

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### ABSTRACT

**Introduction:** in recent years, humanizing care in Intensive Care Units (ICUs) has become a focal point of research worldwide. Key determinants for improving ICU experiences include patient-centred factors (sleep, pain, PTSD prevention), family involvement (visitation policies, communication), and healthcare professional well-being (training, emotional support). This study aims to study the organizational and behavioral characteristics related to humanization and comfort in Italian ICUs.

**Materials and Methods:** a national cross-sectional survey, based on a specific framework, will be conducted from December 2024 to June 2025, involving ICUs' head nurses across Italy.

**Results:** the study will provide a detailed overview of organizational and behavioral practices in Italian ICUs, identifying regional and structural variations, highlighting limitations, and outlining future projects to improve clinical, behavioral, and organizational practices.

**Conclusions:** the national analysis of organizational and behavioral aspects related to humanization in Italian ICUs will focus on the experiences of patients, families, and healthcare professionals. These findings will help to identify best practices and areas requiring improvement, supporting training and organizational interventions to foster a new approach to intensive care.

**Key words:** humanization, intensive care unit, critical care nursing, quality of care, post-intensive care syndrome.

### RIASSUNTO

**Introduzione:** negli ultimi anni, l'umanizzazione dell'assistenza nelle Unità di Terapia Intensiva (UTI) è diventata un punto focale della ricerca a livello mondiale. I fattori determinanti per migliorare l'esperienza nelle UTI includono aspetti incentrati sul paziente (sonno, dolore, prevenzione del disturbo da stress post-traumatico), il coinvolgimento della famiglia (politiche di visita, comunicazione) e il benessere degli operatori sanitari (formazione, supporto emotivo). Questo studio mira ad analizzare le caratteristiche organizzative e comportamentali relative all'umanizzazione e al comfort nelle UTI italiane.

**Materiali e Metodi:** da dicembre 2024 a giugno 2025 sarà condotta un'indagine trasversale nazionale, basata su un quadro specifico, che coinvolgerà i capi infermieri delle unità di terapia intensiva di tutta Italia.

**Risultati:** lo studio fornirà una panoramica dettagliata delle pratiche organizzative e comportamentali nelle unità di terapia intensiva italiane, identificando le variazioni regionali e strutturali, evidenziando i limiti e delineando progetti futuri per migliorare le pratiche cliniche, comportamentali e organizzative.

**Conclusioni:** l'analisi nazionale degli aspetti organizzativi e comportamentali relativi all'umanizzazione nelle unità di terapia intensiva italiane si concentrerà sulle esperienze dei pazienti, delle famiglie e degli operatori sanitari. Questi risultati contribuiranno a identificare le migliori pratiche e le aree che necessitano di miglioramenti, sostenendo la formazione e gli interventi organizzativi per promuovere un nuovo approccio alla terapia intensiva.

**Key words:** umanizzazione, terapia intensiva, assistenza in area critica, post-intensive care syndrome

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## Introduction

In recent years, the issue of humanizing care in Intensive Care Units (ICUs) has gained increasing interest in both national and international research and literature. Numerous studies have explored the importance of enhancing the experience of patients, families, and healthcare professionals in such a highly technical and potentially alienating environment as the ICU.<sup>1</sup> Humanization of care is defined as a process aimed at making the clinical environment more humane, welcoming, and compassionate, not only for patients but also for their families.<sup>2,3</sup> This approach seeks to mitigate the alienating aspects of healthcare by improving patient comfort and emotional experience through greater closeness, understanding, and empathy from healthcare professionals.<sup>4</sup>

The complexity of the ICU environment and clinical interventions significantly impacts the perceived quality of care by patients and their families, as well as post-discharge outcomes.<sup>1,5</sup>

However, cultural and organizational differences across countries make it challenging to generalize findings, highlighting the need for further research in specific contexts.<sup>6</sup> In Italy, for instance, some studies have primarily focused on the adoption of isolated interventions, or the implementation of protocols aimed at improving patient comfort.<sup>7</sup>

A recent study<sup>8</sup> analyzed the quality of life of post-ICU patients, leaving ample room for further investigation into clinical practices and differences in family involvement.<sup>7</sup>

The COVID-19 pandemic further amplified these challenges. Restrictions on visitation policies, many of which remain partially in effect, exacerbated the psychological suffering of patients and their families and underscored the urgency of humanized care practices.<sup>9</sup> These issues were particularly pronounced in Italy, where access policies varied widely across healthcare facilities.<sup>10</sup>

In recent years, the concept of comfort in the ICU has become a key point on quality of care debate, thanks to the holistic approach, reinforcing the need to recognize all stakeholders as active participants in the care process.<sup>11</sup>

Furthermore, the ICU environment presents challenges for healthcare professionals, who frequently experience conflicting emotions such as isolation, sadness, anger, and even joy in response to patient experiences.<sup>12</sup> From the patient perspective, factors such as sleep quality, pain management, and sedation levels should be assessed throughout the ICU stay to guide healthcare professionals in care planning. Additionally, analyzing and preventing post-ICU distress, including Post-Traumatic Stress Disorder (PTSD) and symptoms associated with Post-Intensive Care Syndrome (PICS), are essential for improving care quality.<sup>13</sup>

Family-centered care and open visitation policies are also critical in reducing anxiety and improving comprehension of medical information. Empathetic communication and personalized interactions with family members are crucial for humanizing the ICU environment.<sup>13,14</sup>

In addition, psychological well-being and adequate training of healthcare professionals are essential to maintain a sustainable working environment and ensure high-quality care. Strategies are therefore needed to improve team communication, emotional management, and empathy.<sup>13,15</sup>

The conceptual framework for the holistic approach of discomfort in the ICU shows how the different three perspectives of all ICU stakeholders (patient, family, healthcare professionals) can influence each other experiences and impact on discomfort, family experience e professional well-being.<sup>13</sup>

Despite growing international interest, no national study in Italy has systematically examined how humanization practices are organized and implemented in ICUs.

This study aims to fill that gap by exploring the organizational and behavioural characteristics related to humanized care in Italian ICUs and contribute to the development of evidence-based training and organizational strategies to enhance the comfort and well-being of all ICU stakeholders.

## Materials and Methods

### Study design

A nationwide cross-sectional survey will be conducted using a specifically designed questionnaire. Data collection will take place between December 2024 and June 2025.

### Sample

The survey instrument, named the HumanITA-ICUs (Humanizing Italian Intensive Care Units) Survey, aims to quantitatively describe organizational and behavioral practices in Italian ICUs and will therefore be completed by a coordinator or designated representative from each ICU.

The survey will be distributed across all Italian regions to ensure sample uniformity.

### Survey structure

The survey consists of four main sections based on a specific framework, based on the holistic approach of discomfort in the ICU<sup>13</sup> (Figure 1) and is available online on the official website of ANIARTI (Italian Society of Critical Care Nurses).

A preliminary section gathers contextual information about the respondents' work environment, including ICU type, geographical region, bed capacity, and nursing staff availability.

The first section investigates family access policies in ICUs, distinguishing between partially and fully open models. It also explores any organizational changes following the COVID-19 pandemic and the availability of dedicated family spaces.

The second section examines organizational habits aimed at improving patient comfort in ICUs, including non-pharmacological approaches to enhance sleep quality, systematic delirium assessment, privacy protection, pain management bundles, and the possibility of personalizing patient spaces.<sup>16</sup> It also addresses mobile device use and pet therapy availability.

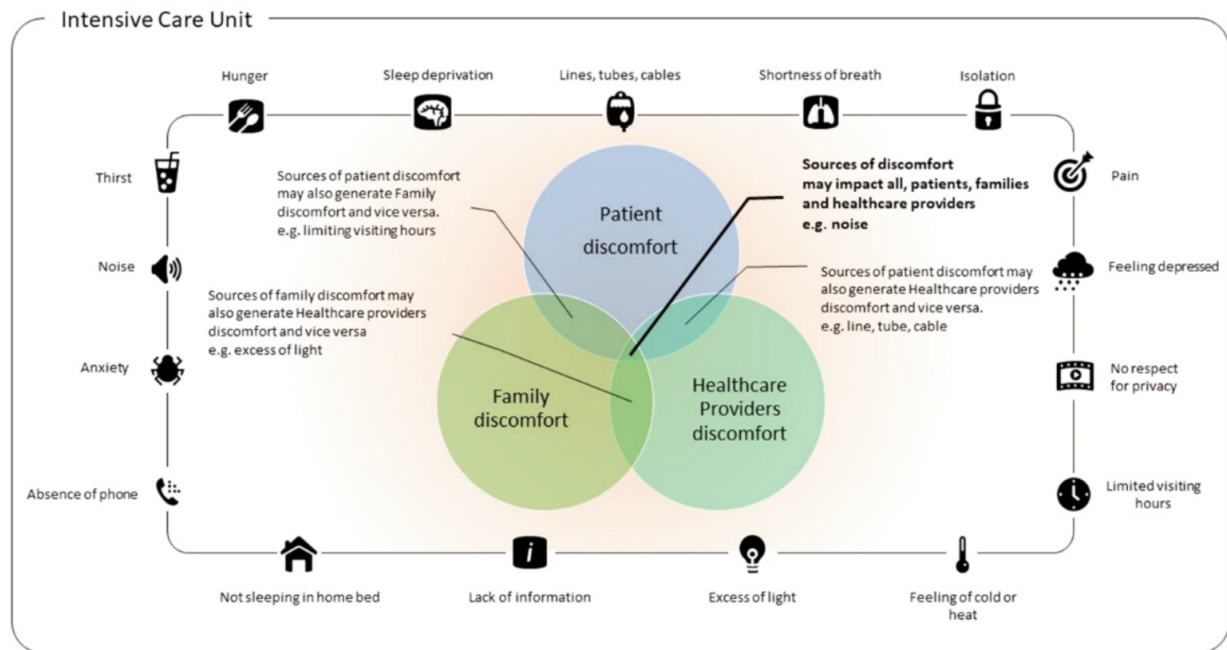
The third section focuses on the experience of patient families, analyzing the use of narrative diaries, structured post-discharge follow-up systems, and digital tools to facilitate communication with intubated or tracheostomized patients.

The fourth section assesses organizational and relational aspects of ICU teams, including structured multidisciplinary briefings, periodic debriefings, and psychological support services for healthcare professionals.

The survey underwent a preliminary face validity assessment involving 10 experienced ICU coordinators affiliated with ANIARTI. Following confirmation of its clarity and relevance, the survey was published.

### Data analysis

Survey data will be entered into an Excel spreadsheet (Microsoft Corp., WA, USA) and undergo quality control by a researcher to ensure accuracy. All responses will remain anonymous, and the questionnaire will explicitly prevent participant identification. Once the target sample size is reached or by June 1, 2025, data will be exported to Excel™ and subsequently analyzed



**Figure 1.** Conceptual framework for an holistic approach of discomfort in the ICU.

using SPSS™ version 27. Descriptive analyses will be conducted to outline the sociodemographic characteristics of the sample. Summary statistics will be presented as absolute frequencies and percentages, for categorical variables, and as medians and interquartile ranges [IQRs] or means and standard deviations for continuous data (according to the Shapiro–Wilk test). Inferential analyses will be performed to identify correlations (e.g., between ICU type and adopted practices) using the Chi-square test for categorical variables and ANOVA or t-tests for continuous normally distributed variables. Statistical significance was established at  $p$  value less than 0.05.

### Ethical considerations

This study will adhere to the Declaration of Helsinki and its subsequent amendments. The research protocol has received approval from the Ethics Committee of the Calabria Region (No. 350/2024, issued on November 27, 2024). Study results will be presented in aggregated and anonymous form, and participation will be voluntary.

### Expected outcomes

The aim of this survey is to provide a detailed overview of organizational and behavioral practices in Italian ICUs, identifying regional and structural variations, highlighting limitations, and outlining future projects to improve clinical, behavioral, and organizational practices.

### Limitations and strengths

Voluntary participation may introduce selection bias and lead to an uneven representation of different regional contexts. Additionally, variations in ICU structures and organizational practices may limit the generalizability of results, necessitating further contextual analyses.

### Reporting of the results

The results of the survey study will be reported according to the reporting guideline ‘A Consensus -Based Checklist for Reporting of Survey Studies (CROSS)’<sup>17</sup> and the recommendations published by Latour and Tume (2021).<sup>18</sup>

### Implications for the profession

The findings will be instrumental in mapping organizational and behavioral practices related to humanized ICU care in Italy, serving as a foundation for training needs and improvement initiatives to enhance patient and family comfort and improve short and long-term physical and emotional outcomes of patients and families (Post-Intensive Care Syndrome).

### Conclusions

This study will provide a comprehensive analysis of organizational and behavioral aspects related to humanization in Italian ICUs, focusing on the experiences of patients, families, and healthcare professionals. The findings will help identify best practices and areas requiring improvement, supporting training and organizational interventions to foster a new approach to intensive care.

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Conflict of interest: the authors declare no potential conflict of interest, and all authors confirm accuracy.

Ethics approval: the research protocol has received approval from the Ethics Committee of the Calabria Region (No. 350/2024, issued on November 27, 2024). Study results will be presented in aggregated and anonymous form, and participation will be voluntary.

Availability of data and materials: all data generated or analyzed during this study are included in this published article.

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