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About the journal

Interdisciplinary Journal of Nursing and Health (IJNH) is a continuation of *Infermieristica Journal* (eISSN 2785-7018). IJNH is an international, peer-reviewed, open-access scientific journal dedicated to advancing rigorous and globally relevant scholarship in nursing and health sciences. *Interdisciplinary Journal of Nursing and Health (IJNH)* promotes the development, integration, and exchange of knowledge that informs nursing research, clinical practice, and health policy. The journal supports evidence-based practice and fosters critical debate on contemporary issues related to the art and science of nursing. IJNH particularly welcomes studies that seek to evaluate and understand complex health care interventions, health systems, and health policies, using the most rigorous and appropriate research designs. The journal also aims to strengthen the methodological quality of health research by publishing high-quality methodological papers that introduce or refine analytic approaches, measurements, or research methods. All submissions undergo double-anonymized peer review, and IJNH publishes original contributions of relevance to the international health care community. IJNH is a fully open-access journal, accessible to readers worldwide without subscription or publication fees. The journal is published in English.

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Connecting Disciplines, Transforming Health: The Vision of the Interdisciplinary Journal of Nursing and Health

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Welcome Interdisciplinary Journal of Nursing and Health!

We are at the beginning of a journey and we launch the Interdisciplinary Journal of Nursing and Health (IJNH) with an ambitious vision: to create a space where diverse health disciplines meet, integrate, and generate shared knowledge and practice for the wellness of people we care for.

This journal emerges from the recognition that the complex health challenges of our time demand collaboration across traditional boundaries, bringing together all healthcare disciplines (nursing, medicine, psychology, sociology, public health, technology, bioethics, environmental science, humanities etc.) in dialogue. The IJNH positions itself as a global platform for scientific exchange that embraces contextual diversity, values methodological plurality, and advances an impactful science. We are committed to promoting research that not only describes reality but helps transform it — research that connects, empowers, and drives cultural and political change.

The IJNH represents the evolution of *Infermieristica Journal*, which for three years has served as a vital platform for nursing scholarship, supporting research capable of engaging both national and international scientific communities. Under the distinguished leadership of Professor Laura Rasero, *Infermieristica Journal* fostered a nursing scholarship that was open, rigorous, and continuously evolving, building a reputation for scientific excellence and commitment to evidence-based practice. We extend our deepest gratitude to Professor Rasero for her vision, dedication, and the solid foundation she established — a foundation upon which the IJNH now builds. This transformation reflects not an abandonment of nursing's roots, but rather their natural extension into new territories, where nursing science can engage more fully with the complex, multifaceted realities of contemporary healthcare.

The Imperative for Interdisciplinarity

We live in an era where science must move swiftly — yet with depth, responsibility, and

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purpose. Global health challenges demand a vision that transcends disciplinary and professional boundaries. The increase of chronic diseases, the climate changes, the growing health inequities, immigration, and the digital transformation of healthcare have demonstrated unequivocally that isolated disciplinary approaches are insufficient to address nowadays' challenges. Health is not the exclusive domain of any single profession but it is the intersection of biological, psychological, social, cultural, economic, and environmental factors. The nurse who understands sociological perspectives is better equipped to address health disparities; the physician who engages with nursing's holistic approach to patient care provides more comprehensive treatment; the health policy researcher who collaborates with frontline practitioners creates more implementable solutions. The IJNH was created to build a scientific environment where nursing naturally interacts with medicine, psychology, sociology, public health, technology, bioethics, environmental science, and the humanities, acknowledging health as a complex, collective, dynamic phenomenon.

Our Mission and Vision

Our mission is to promote research that describes reality, but above all helps transform the everyday experience of people and communities. We believe that knowledge takes its fullest meaning when it touches lives, influences decisions, and connects professionals around shared values.

At IJNH we will be happy to publish papers that:

- Bridge health disciplines by bringing together researchers from nursing, medicine, allied health professions, social sciences, humanities, and beyond to address shared concerns;
- Emphasize and integrate diverse methodologies by valuing quantitative, qualitative, and mixed-methods approaches, recognizing that different questions require different tools and different ways of listening to reality;
- Engage with practice by ensuring research remains grounded in the lived realities of patients, families, communities, and healthcare professionals;
- Embrace global perspectives by welcoming contributions from all geographical contexts and cultural traditions and by recognizing the richness that diversity brings to scientific dialogue;
- Advance innovation by exploring emerging technologies, novel interventions, and creative solutions to persistent problems
- Demonstrate impact by articulating clear pathways through which knowledge translates into improved health outcomes, policy change, or enhanced practice.

What We Publish

The IJNH welcomes a broad range of scholarly contributions that advance our understanding of health, illness, healing, and care in all their human, social, and relational dimensions:

- Original research articles employing diverse methodologies to investigate health phenomena, interventions, outcomes, or systems, with a special interest in studies that illuminate the complexity of real-world contexts;
- Research protocols describing planned studies to promote transparency, reproducibility, and early-stage scientific collaboration;
- Review papers synthesizing evidence across disciplines and identifying gaps in current knowledge while offering reflections that guide future directions;;
- Commentaries offering critical analyses of emerging issues, policies, or debates in health and healthcare with the courage to challenge assumptions and spark dialogue;
- Letter to the Editor commenting published papers to emphasize the science dialogue;
- Case reports, case series and practice innovations describing and evaluating novel approaches to care delivery, education, or leadership that emerge directly from clinical wisdom and frontline experience;
- Guidelines and consensus statement focusing on health challenges and solutions in diverse international contexts

We particularly encourage submissions that explicitly engage with multiple disciplinary perspectives, that address all health issues, that center patient and community voices, or that grapple with the ethical dimensions of health research and practice.

An Invitation to Our Community

We are particularly grateful to all nursing authors who have supported *Infermieristica Journal* over the years and we invite them to continue sharing their research. At the same time, we welcome to the IJNH also the contributions of scholars from medicine, public health, psychology, sociology, social work, pharmacy, rehabilitation sciences, and other health-related fields.

We invite also students and emerging scholars to submit their works as we are committed to nurturing the next generation of interdisciplinary health scientists. The IJNH encourages you to see this journal as a platform for developing your voice within the broader health science community.

Finally, we invite also practitioners, policymakers, and community partners to submit their works because we believe that knowledge creation must involve those who live and work at the intersection of theory and practice. We welcome practice-based scholarship and contributions that bridge the research-practice gap.

Looking Forward

The Interdisciplinary Journal of Nursing and Health does not replace another journal but evolves. It is the continuation of a journey, and the affirmation of a vision: a health science that thinks together, acts together, grows together. As we launch this new chapter, we do so with humility about the challenges ahead and enthusiasm for the possibilities it creates.

We envision a journal that becomes known not only for the quality of its scholarship but for its contribution to solving real-world health problems. We aspire to be a venue where meaningful dialogue occurs across differences, where innovative ideas are nurtured, and where evidence is translated into action. We commit to supporting open science practices, promoting equitable access to knowledge, and maintaining the highest ethical standards in all aspects of our work.

The health challenges of the 21st century require nothing less than our collective intelligence, creativity, and commitment. As we open the pages of this first issue of IJNH, we invite you to join us in building a more integrated, more

responsive, and more impactful health science.

Together, we can advance knowledge that truly serves health — in all its complexity, diversity, and possibility.

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Investing in Young Nurses Worldwide: If Not Now, When? The Importance of Promoting the New Generations in the Healthcare System

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The world stands at a decisive crossroads in the aftermath of a global pandemic that exposed the fragility of health systems and highlighted the indispensable role of nurses. The question before us—if not now, when? —is not rhetorical. It is a call to action, a challenge to political leaders, academic institutions, and healthcare organizations to invest, meaningfully and sustainably, in the next generation of nurses.

According to the World Health Organization (WHO), the world will face a shortage of nearly 13 million nurses by 2030 if current trends continue (Buchan J, Catton H, Shaffer F, 2022; WHO, 2020; WHO, 2016). The crisis is not only quantitative but profoundly qualitative: young nurses are entering the profession amid burnout, moral distress, and systemic under-recognition. Many nurses leave within the first five years of practice (De Vries N, et al., 2024). The result is a self-perpetuating cycle, one that threatens the very fabric of healthcare delivery, especially in low- and middle-income countries.

Investing in young nurses means far more than recruiting more staff. It means creating environments where early-career professionals can thrive, not merely survive. Competitive compensation, opportunities for advanced education, structured mentorship, and pathways to leadership are fundamental. Equally essential are supportive workplaces where mental health is prioritised, professional autonomy is respected, and diversity and innovation are actively encouraged (Abdul Rahim H et al., 2022, WHO, 2021).

We also need to rethink how we train nurses for a world that is changing quickly. The health challenges of the 21st century such as climate change, antimicrobial resistance, digital transformation, and global mobility, require a workforce equipped with critical thinking, adaptability, and cross-cultural competence. Academic programs must integrate evidence-based practices with ethical leadership and policy advocacy. Young nurses should not be

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trained to follow but to lead.

This investment is not optional. It is the foundation for resilient health systems and equitable care. Each nurse represents a bridge between science and humanity, between policy and practice. When young nurses are empowered, the benefits ripple outward: strengthening communities, improving health outcomes, and inspiring trust in health institutions (American Nurses Association, 2022).

The world applauded nurses in 2020, the International Year of the Nurse and Midwife. Yet applause, without action, fades quickly. The moral imperative now is to transform recognition into investment and commitment into sustained change.

If not now—when?

The Spanish Situation

These global trends are not abstract. They materialize with intensity in national contexts, where demographic shifts, workforce shortages, and structural limitations collide. Spain illustrates this dynamic vividly and reflects a broader European challenge. It is expected that in the next 10 years around 50,000 nurses will retire. Although the number of new professionals has remained steady in the country, with around 10,000 new nurses graduating each year, the projected retirements will not be enough to reach an adequate workforce, as there is already a current shortage of 100,000 nurses. Furthermore, many nurses leave the profession for different reasons, worsening the lack of healthcare personnel (Galbany-Estragués P., 2024; Zamora J., 2024). This shows the critical situation currently faced, and it is just another example of what is happening in other European countries.

In this context, newly graduated nurses face a dual situation: on the one hand, thanks to progress, there are many opportunities for professional growth due to the increasing professionalization of the profession; on the other hand, unfortunately, there is a widespread sense of pessimism about the current and future outlook (Gutiérrez Martí R. et al., 2023).

This raises the question... who will replace those nurses who have been leaders in the profession and who have helped transform nursing, driving it forward significantly in just a few years? Who will be the next referents of the profession? Who

will ensure the transfer of this legacy? With the retirement of many senior nurses, one problem is becoming increasingly evident: a great deal of experience and knowledge in teaching, clinical practice, and management is being lost, and there are not enough emerging talents to receive it.

This leaves us with a twofold challenge: on the one hand, the clear need to increase the number of nurses, but at the same time, the need to also promote the talent of new generations, as both a response and a solution to future challenges and to the advancement of the profession (Oliete C. et al., 2025).

If this is not done, we will face the problem that increasing the number of nurses alone is not enough if they are not supported in developing a proactive attitude, a critical mindset in clinical practice and research, and a spirit of non-conformity. It is therefore essential to identify young talents and help them take off with the support of those with more accumulated experience.

Generational renewal will only happen if knowledge transfer can fall upon *“a vessel ready to receive it.”*

Moreover, this is not only a responsibility to secure a future committed to advancing the profession, but also an opportunity for both seniors and juniors to benefit from what each of them lacks. This reality is not unique to Spain. Similar trends can be observed elsewhere in Europe, such as Italy.

The Italian Situation

Italy offers another example of how this crisis unfolds at the national level. Here, the time for symbolic recognition has passed. It also faces challenges that resonate across the international nursing community. In Italy, nurses constitute approximately 40% of the National Health Service (SSN) workforce and play a pivotal role in ensuring the effectiveness, continuity, and quality of care (FNOPI, 2025). Many studies, particularly the RN4CAST project (Sasso L. et al., 2017; Bagnasco A., 2024), have demonstrated that employee well-being is closely associated with the quality of care provided to patients. Work conditions have a big impact on nurses' organizational well-being (Della Bella et al., 2024). Well-being is also correlated with indicators that significantly influence the overall efficiency of

the healthcare system, such as turnover and absenteeism rates. An increasing number of nurses are considering leaving the profession or seeking opportunities in other national or international contexts, thereby exacerbating an already critical staffing shortage.

Addressing this trend requires improving the working conditions of current staff, reducing turnover, and enhancing the sustainability and attractiveness of the profession. According to the most recent report published by the National Federation of Nursing Orders (FNOPI), several critical issues emerge (FNOPI, 2025):

- A nurse-to-population ratio below the international average, with substantial regional variability in the public sector.
- Remuneration levels are lower than the European average and heterogeneous across regions, largely due to disparities between managerial and non-managerial positions.
- Limited representation of nurses in strategic leadership roles within healthcare organizations. Limited clinical career opportunities.
- Approximately 50% of nurses report being fully satisfied with their job, although satisfaction varies significantly by clinical setting, ranging from 25% to 70–80%.
- Systematic assessments of patient satisfaction with nursing care remain limited.

The loss of personnel has been gradual and persistent. One consequence of reduced turnover is the progressive ageing of the SSN workforce (FNOPI, 2025).

In 2024, FNOPI reported 458,112 registered nurses. Overall, the demographic profile reveals a relatively mature workforce, peaking in the 51–55 age range, and a limited presence of younger professionals. This highlights the need for targeted strategies to support generational renewal and increase the attractiveness of the profession (FNOPI, 2025).

The data presented underscore the current crisis facing the nursing profession, characterized by high turnover, intention to leave, and, in some cases, complete abandonment of the career. It is essential to initiate processes capable of producing tangible improvements in daily clinical practice through education and professional development. The profession remains insufficiently attractive, and a sense of disaffection persists, with nurses perceiving that

their expertise is not yet fully recognized (SIDMI, 2025).

The UK Situation

While Italy underscores the urgency of systemic investment, the United Kingdom brings yet another perspective to this shared global challenge—one shaped by reliance on international recruitment, early-career attrition, and the need for sustainable workforce strategies.

The nursing workforce in the UK is at a critical stage. Despite the Nursing and Midwifery Council (NMC) reporting high registration figures in 2025, this seeming increase masks a dependence on internationally educated nurses and ongoing local attrition (NMC, 2025). Almost fifty percent of new registrations originate from other countries, with international recruits maintaining NHS staffing levels while UK-trained nurses depart at concerning rates (NMC, 2025). Early-career turnover is alarming, with nearly one-third of nurses departing within the initial five years of registration, attributing their decision to leave to fatigue, poor workplace culture, and insufficient support (Royal College of Nursing, 2025; The Health Foundation, 2024). These losses signify a substantial failure in the return on investment for both educational financing and service delivery, jeopardising the continuity of care in communities with increasing health disparities.

The loss of internationally educated nurses exacerbates the problem. Numerous individuals describe discrimination, visa instability, and unmet expectations, resulting in rising turnover rates within three years (Royal College of Nursing, 2025). This cycle of hiring and attrition is unsustainable. Communities require stable, locally embedded teams that mirror their demographics and foster enduring trust, rather than a transient workforce influenced by temporary recruiting initiatives.

Consequently, investing in and advocating for the future workforce is essential. Enhancing domestic training capacity, facilitating early-career transitions, and implementing retention strategies—such as designated study leaves, mentorship, and flexible work arrangements—can significantly improve morale and workforce sustainability (NHS, 2024). A balanced strategy that appreciates both domestic and international talent will be essential for the NHS and other healthcare sectors in Britain to provide safe,

equitable, and person-centered care for everyone.

The time for symbolic recognition has passed. What the nursing profession needs today is tangible, measurable action. Investing in young nurses must move beyond rhetoric to become a shared global priority embedded in policies, budgets, and institutional strategies. This means implementing frameworks that ensure equitable pay, safe staffing ratios, career advancement opportunities, and the integration of nurses into decision-making at every level of healthcare governance.

Global early-career leadership networks, such as the Nursing Now Challenge (NNC) are crucial in mentoring, empowering, and supporting the next generation of nurses and midwives worldwide. These platforms provide early-career professionals with the opportunity to cultivate leadership skills, participate in policy conversations, and establish international collaborations that enhance the global health workforce. Their work illustrates how organized mentoring and international knowledge sharing can expedite professional development and motivate future nursing and midwifery leaders.

Governments, academic institutions, and healthcare organizations must collaborate to elevate the nursing profession to a realm of development, innovation, and leadership. International cooperation, mentorship networks, and investment in higher education are essential for cultivating a workforce equipped to address future health concerns. Supporting and growing programmes such as the Nursing Now Challenger Committee, from the NNC, is vital for developing a resilient, future-ready nursing and midwifery workforce.

Recognising the value of nursing also means protecting its future. Every action that enhances the visibility, autonomy, and expertise of young nurses strengthens the entire healthcare system. Investing in them is not merely an act of professional support, it is an act of public health, social justice, and human solidarity.

Taken together, these national snapshots reveal a single truth: without decisive investment in young nurses, health systems worldwide risk becoming unsustainable. If we truly believe that nurses are the backbone of healthcare, then our next step must be clear: turn words into action, and recognition into transformation. Because the question remains—if not now, when?

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Emergency Department Boarding: An Inevitable Phenomenon or Crucial Quality Indicator?

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The phenomenon of boarding in emergency departments has represented one of the most significant challenges for contemporary healthcare systems over the past 30 years. (Pines, 2025; Sartini, 2022). The term "boarding" refers to the patient's stay in the emergency department after the decision to admit them while awaiting a hospital bed (Iozzo et al., 2024; Sartini, 2022). This interval is now recognized as a critical element in hospital management with both clinical and organizational implications (Joseph et al., 2024). International literature has highlighted that boarding cannot be considered a mere side effect of emergency-urgent care activities but rather a potential indicator of the quality and safety of care (Sartini, 2022; Singer, 2011). In a study conducted in Israel, over 250,000 emergency department visits were analyzed over five years. This is a large sample, allowing for precise observation of clinical dynamics. Among all these patients, approximately 1,200 experienced a documented clinical error, and here comes the crucial data: 61% of these patients were boarding. The question arises as to whether it should be interpreted as an unavoidable phenomenon inherent in the complexity of healthcare systems or as a key

parameter for evaluating the efficiency and quality of care (Kolikof, 2025). In recent decades, numerous healthcare systems have reduced the number of hospital beds, moving towards a model of community-based healthcare and public spending containment (Pines, 2011). This reduction, while justified by economic sustainability goals, has increased pressure on hospitals, contributing to patient accumulation in emergency departments. The progressive aging of the population leads to an increase in demand for hospital admissions and the clinical complexity of cases (Joseph et al., 2024). Furthermore, numerous studies have confirmed that older and frail patients require longer hospital stays, thus reducing bed availability for new admissions (Lewis, 2020; O'Caoimh et al., 2019). Another determinant is the difficulty in ensuring timely and safe discharge. The lack of facilities such as hospices or concrete alternatives in the community for consistent care continuity slows downward turnover, generating cascading congestion in emergency departments (Kolikof, 2025). Seasonal epidemics, heatwaves, and other sudden emergencies produce exceptional access flows to emergency departments, further exacerbating the already fragile system.

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Admission is frequently perceived as the responsibility of the emergency department, but it is not. Rather, it is a matter related to hospital productivity, staff availability, and correct resource allocation (Sartini, 2022). The shortage of nursing staff and closure of hospital beds have widened this gap. Emergency departments are the release valves of a system that no longer has room to maneuver (Pines, 2025). Boarding contributes to overcrowding in emergency departments, hindering the care of new patients and increasing staff workload. This phenomenon generates professional stress, burnout, and a reduction in the perceived quality of care (Pines, 2011). From an ethical standpoint, holding patients for prolonged periods in environments not designed for inpatient care raises issues of dignity, equity, and distributive justice, as frail individuals are disproportionately penalized (García-Peña, 2018; Iozzo et al., 2025; Singer, 2011). Boarding has documented consequences for the quality of care and clinical outcomes (Joseph et al., 2024). Numerous studies have highlighted an association between prolonged boarding times and an increased risk of adverse events, including falls, healthcare-associated infections, and death (Boudi et al., 2020; Joseph et al., 2024; Lewis, 2020; Olson et al., 2024; Pines, 2025). In a study conducted on 1,406 adults aged ≥ 60 years, admitted to two general hospitals in Mexico City (García-Peña, 2018), the mortality recorded in the sample was 21.8%. The analysis showed that the duration of boarding is associated with an increased risk of death; each additional hour spent in the emergency department increases this risk. Some authors argue that boarding is inevitable within certain limits. In a complex system, characterized by limited resources and variable demand, moments of congestion are physiological (Boudi et al., 2020; Joseph et al., 2024; Singer, 2011).

From this perspective, boarding constitutes an acceptable compromise. However, this view risks legitimizing a condition that, if prolonged, compromises patient safety and quality of care. Therefore, considering boarding as an unavoidable phenomenon can translate into a form of managerial abdication of responsibility. Conversely, an increasingly widespread perspective interprets boarding as a crucial indicator of quality (Coil, 2016; Kolikof, 2025; Mohr et al., 2020; Sartini, 2022). Reduced boarding times testify to the efficiency of admission and discharge processes,

coordination capacity between the emergency department, wards, and community services, and effectiveness of hospital governance. In this sense, boarding can be likened to a "litmus test" for the healthcare system: its extent reflects the quality of the organization and the structural and managerial resilience of the hospital. Numerous international experiences have shown that boarding can be reduced through targeted strategies, such as centralized bed management (e.g., bed manager), planned discharges, strengthening of community care, and predictive flow analysis (Coil, 2016; Joseph et al., 2024; Pines, 2011; Sartini, 2022). Therefore, boarding in the emergency department constitutes a complex phenomenon at the crossroads of hospital organization, healthcare planning, and patient safety. While a minimum level may be considered physiological, boarding must not be accepted as an inevitable outcome. In contrast, it represents a crucial quality indicator that is useful for monitoring system efficiency and guiding improvement policies. Addressing boarding implies a systemic approach that integrates internal hospital organizational strategies aimed at accurate bed management with interventions to strengthen community care. Only a comprehensive vision oriented towards efficiency and dignity of care can reduce the incidence of this phenomenon and ensure safer, higher-quality assistance.

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EDUcation, HEalth Literacy and Stroke in European Countries: EDUHELP Project

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Abstract

Objectives. The EDUHELP project aims to (1) assess stroke-related health literacy (HL) in the general populations of Albania and Italy and identify sociodemographic and behavioral determinants of low HL, and (2) linguistically and psychometrically validate stroke-related HL questionnaires for cross-cultural use in both countries.

Trial Design. This is a cross-sectional, two-phase, multicentre observational study. Phase 1 consists of a population-based survey to estimate levels and determinants of stroke-related HL. Phase 2 focuses on the linguistic, cultural, and psychometric validation of the instruments, following COSMIN and SPIRIT recommendations for measurement studies.

Participants and Settings. Approximately 1,000 adults (≥18 years) will be recruited in each country using a stratified convenience sampling approach with quota targets for age, sex, geographic region, and urban–rural residence. Participants will be recruited in public settings and through an online survey. Healthcare professionals and individuals unable to provide informed consent will be excluded.

Interventions. This is an observational study with no clinical intervention. Participants will complete a structured questionnaire including a sociodemographic survey, the Stroke Knowledge Test, the Awareness of Stroke Symptoms and Risk Factors Questionnaire, and the Stroke Risk Factor Knowledge and Perception Questionnaire. Questionnaires will undergo forward–backward translation, cognitive pretesting, and expert content validation.

Primary and Secondary Outcomes. The primary outcome is a latent stroke-related HL score derived from confirmatory factor analysis of combined questionnaire items. Secondary outcomes include identification of HL predictors through weighted multivariable regression models and evaluation of psychometric properties (content validity, reliability, factor structure, and measurement invariance across countries).

Conclusions. EDUHELP will provide population-level evidence on stroke-related HL in two European countries with differing healthcare contexts and deliver validated tools for cross-national HL assessment, supporting future public health education and prevention strategies.

Keywords: Health Literacy, Stroke, Cross-Sectional Study, Protocol, Validation, European Country

Introduction

Globally, it is estimated that between 10% and 15% of all early strokes occur in individuals aged 18 to 50 years (Ekker et al., 2018), leading to neurological deficiencies in motor, sensory, and cognitive functions (Wang et al., 2023). Despite the improvement in the prevention and treatment of cardiovascular diseases, studies (Chang et al., 2021; Ekker et al., 2018; Pandian et al., 2018) have suggested an increase in the incidence of stroke in young adults, in contrast to the decline observed in the elderly population (Ekker et al., 2019). While the incidence of stroke is decreasing in high-income countries, incidence rates have risen in low- and middle-income countries (Kono et al., 2023).

To understand the general knowledge of the population about stroke, it is essential to assess health literacy (HL) (Korv et al., 2013), defined as the degree to which individuals can access, understand, evaluate, communicate information that is necessary to promote and maintain good health throughout life (Nazar et al., 2019), as well as implement medical instructions and package inserts (Alimehmeti et al., 2016). As described in the literature, HL significantly impacts health outcomes (Cajita et al., 2016). HL is a factor that can influence the control and prevention of stroke recurrence through patient follow-up care (Sanders et al., 2014). However, the relationship between HL and incidence of stroke remains not fully understood (Sanders et al., 2014), and there is a substantial knowing-doing gap in stroke prevention (Faiz et al., 2019).

Benoit et al assessed, for the first time the

effectiveness of a one-year pre-discharge educational intervention for stroke and found that knowledge of risk factors and warning signs improved within three months (Benoit et al., 2020). Improving stroke literacy may also be crucial in reducing stroke-related disparities (Ravenell et al., 2015).

Although several studies analyzed HL in chronic diseases (Gazmararian et al., 2003; Liu et al., 2020), there is lack of knowledge about HL in general population about stroke, particularly in low-middle countries in Europe. Understanding the level of HL also in Europe is especially important, as stroke remains a leading cause of death globally, with the burden rapidly increasing and resulting in an annual cost of 60 billion of euros (Luengo-Fernandez et al., 2020). It is essential to understand the clinical risk factors, evaluate health behaviors and raise awareness of sudden stroke symptoms. While improving HL in the general population can be challenging, as it requires changes in health behaviors, it is of utmost importance (Gibson et al., 2022). Studying HL levels in Albania and Italy can help identify knowledge gaps in the public's understanding of stroke, and determine how individuals would respond in the event of a stroke (Matsumoto et al., 2020). An accurate assessment of HL regarding stroke is critical to identifying predictors of low HL (Bitzer & Sorensen, 2018). By identifying these predictors, interventions can be developed to enhance HL levels, promote appropriate behaviors, and reduce the risk of stroke onset (Bitzer & Sorensen, 2018).

Comparing stroke HL between Albania and Italy requires consideration of several factors,

including the education system, healthcare infrastructure, cultural context, and access to health information. Italy has a more developed healthcare system, more accessible public health campaigns, and higher levels of stroke literacy, with a general public more aware of stroke risks and symptoms (Giulio de Belvis et al., 2022). In contrast, while Albania has made strides in healthcare, it faces challenges in public health awareness, access to medical information, and education, which can result in lower stroke literacy compared to Italy (Lalo et al., 2023; Mustaqe et al., 2023). In Albania the burden of stroke has been rising over the years (Lalo et al., 2023). Given that stroke is a major public health issue in both countries, there are likely significant differences in stroke HL due to variations in healthcare systems, education, public health campaigns, and overall HL levels.

Improving HL among citizens can be challenging, as it often requires changes in health behaviors, but it is of utmost importance (Gibson et al., 2022). Studying the level of HL in Albania and Italy could help to better understand the general public's knowledge of stroke, identify potential gaps in the literature, and assess how people would respond in the event of a stroke. An accurate assessment of HL regarding stroke is essential for identifying predictors of low HL (Bitzer & Sorensen, 2018). Identifying these predictors allows for the development of interventions aimed at increasing knowledge and promoting behaviors that reduce the risk of stroke onset (Bitzer & Sorensen, 2018).

Objective

The aim of this EDUHELP protocol is to describe HL regarding stroke in European countries, specifically Albania and Italy. Two specific objectives have been developed:

Aim 1: To assess the level of HL related to stroke in the Albanian and Italian populations. This will involve ranking the distribution of HL across various regions, conducting correlation analyses, performing regression analysis to identify risk factors, and determining which subgroups within the population exhibit low HL levels. Additionally, the most vulnerable groups will be identified, along with their predictors.

Aim 2: To linguistically and culturally validate questionnaire for assessing HL related to stroke.

Methods

This study will adopt a cross-sectional design as part of the EDUHELP protocol. The protocol has been structured following the recommendations of Meursinge Reynders R. et al. (2017) (Meursinge Reynders et al., 2017) to ensure comprehensive protocol planning for cross-sectional studies. The first phase of the observational study will be reported according to the STROBE guidelines (Cuschieri, 2019; Vandenbroucke JP et al., 2007), as it is a study protocol for a cross-sectional survey. The second phase of the investigation will follow the COSMIN (Consensus-based Standards for the selection of health status Measurement INstruments) checklist to assess the methodological quality of the psychometric properties in the cross-cultural adaptation of the scale (Mokkink et al., 2006; Mokkink LB et al., 2025). The timeline for the conduct of the study is described in detail in the Figure 1 and 2. In detail, Table 1 outlines the planned operational workflow of the EDUHELP project, specifying activities, timing, and responsibilities in accordance with SPIRIT 2013 recommendations for cross-sectional studies. The schedule provides transparent information on enrolment, translation, data collection, validation, and analysis activities. The study was approved on October 11 2021 by the Ethics Committee of the Catholic University Our Lady of Good Counsel," Tirana, Albania (Approval Nr° Pr.362/2021). The protocol adheres to the principles of the Declaration of Helsinki (2013 revision) and the European Union General Data Protection Regulation (GDPR 2016/679).

Setting and sample

The study will involve residents of Albania and Italy, with approximately 1,000 participants aged 18 and older recruited from each country. Recruitment will occur in public places (e.g., streets, cafés, hospitals), and two interviewers (MY and FK) will conduct in-person surveys to assist older adults who may have difficulty understanding the questions or using the internet. An online questionnaire will be available for younger, digitally-savvy participants. To improve representativeness, quota targets will be applied within each country to ensure a balanced distribution of participants by age group (18–34, 35–54, ≥55 years), sex (male/female), geographic region (north/center/south in Italy; north/center/

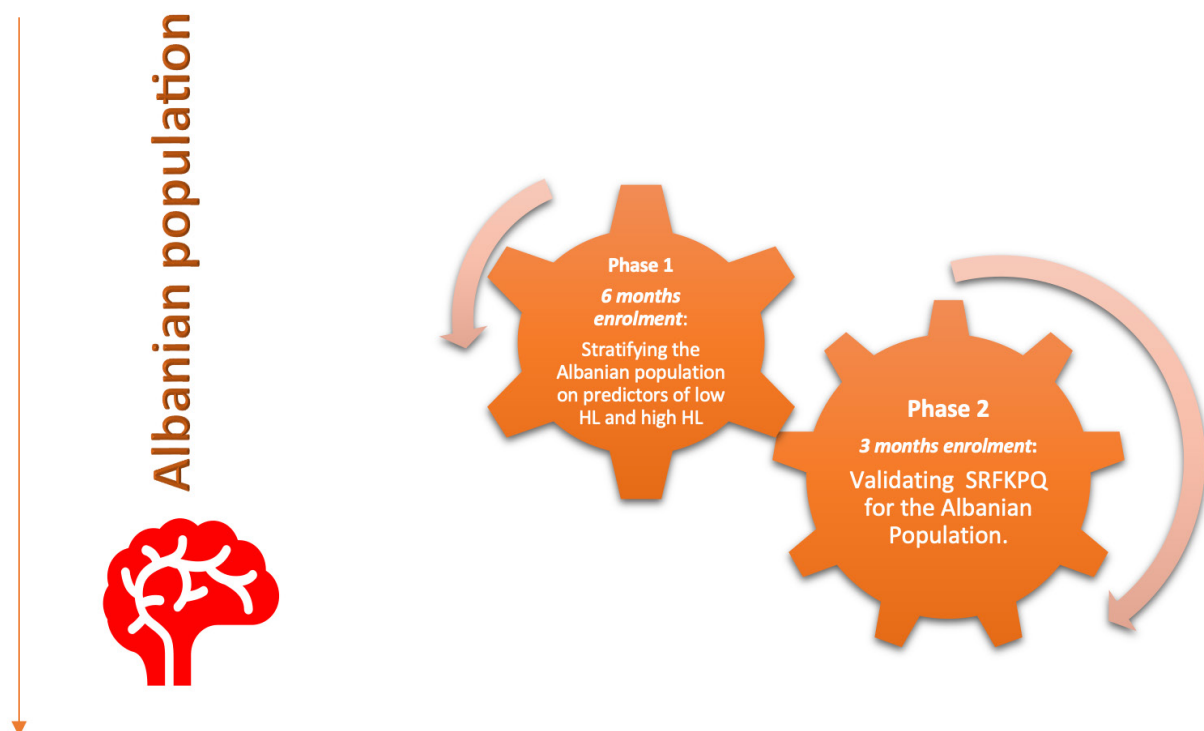


Figure 1. Chronology of the study phases of the EDUHELP project on the Albanian population.

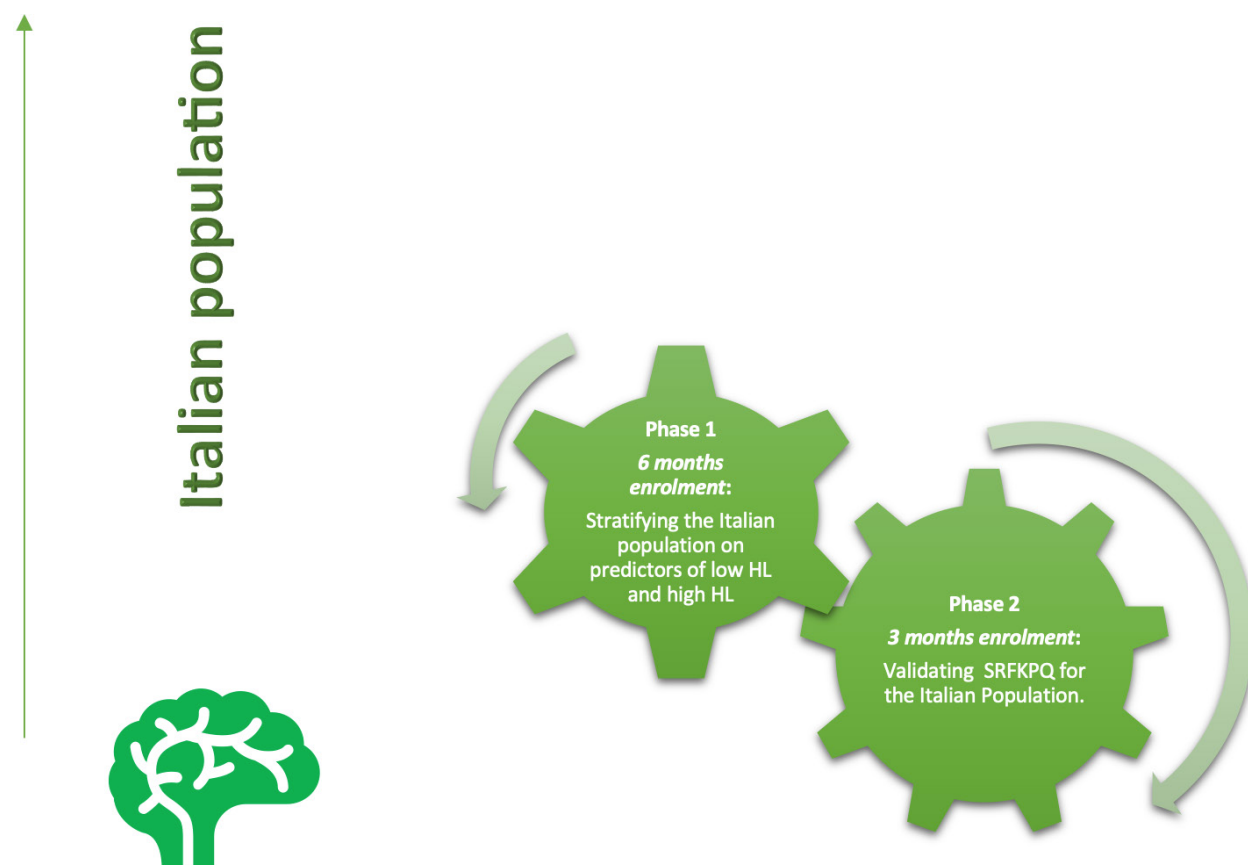


Figure 2. Chronology of the study phases of the EDUHELP project on the Italian population.

Table 1. SPIRIT-style operational timeline of the EDUHELP protocol (months counted from study initiation).

Study phase / activity	Time window	Country	Responsible team	Description and Outputs
Preparation phase	Months 0–2	Albania, Italy	Principal investigators; bilingual translators	Translation and back-translation of SKT, Awareness, and SRFKPQ tools; ethics submission and approvals.
Pre-testing	Month 3	Both	Senior researchers; 2 field interviewers	Cognitive pre-test on ~32 participants to assess comprehension and equivalence.
Phase 1 – Population survey	Months 4–9	Albania, Italy	Field interviewers (2 per country); supervisors	Cross-sectional data collection (~1,000 participants per country); quota-controlled convenience sampling.
Data cleaning and verification	Months 10–11	Both	Data manager, statistician	Quality control, missing data analysis, MI setup.
Phase 2 – Validation study	Months 12–14	Both	Psychometric analysis team	CFA and measurement invariance testing for SRFKPQ and related instruments.
Statistical analyses and reporting	Months 15–17	Both	PI, biostatistician	Weighted regression, sensitivity analyses, preparation of manuscript.
Dissemination and archiving	Months 18–20	Both	PI, co-investigators	Results submission, anonymization, destruction of linkage key.

south in Albania), and urban–rural residence. Recruitment will continue until each quota cell is approximately filled. This stratified convenience approach aims to mitigate selection bias inherent in non-probabilistic sampling. Quota cells will be defined by the cross-classification of sex (male/female) $\times$ age group (18–34, 35–54, ≥ 55 years) $\times$ region (north/center/south) $\times$ area of residence (urban/rural), yielding $3 \times 2 \times 3 \times 2 = 36$ cells per country. The targeted number of respondents in each cell will reflect the relative population proportions derived from official national statistics (Fund, 2024; ISTAT, 2024). Within each country, recruitment will proceed sequentially until each quota cell is filled to within $\pm 5\%$ of its expected share, ensuring approximate balance across strata (Division, 2005).

Post-stratification (raking) weights will subsequently be computed to align the achieved sample distributions with the national population margins for sex, age, macro-region, and urban–rural residence using iterative proportional fitting. Weights will be normalized to retain the original sample size ($\Sigma w = N$) and applied in all descriptive and regression analyses to yield population-representative estimates (Lumley, 2010).

Weighted analyses will constitute the main analytical results, while unweighted analyses will be reported as sensitivity checks to evaluate potential bias from differential non-response or over-representation of specific strata (Lumley, 2010).

Health professionals are excluded to avoid professional knowledge bias, as their exposure to stroke-related information and health campaigns differs substantially from that of the general population, which could artificially elevate average HL estimates. The focus of this study is to describe HL among lay citizens.

Exclusion criteria include non-citizens of Albania or Italy, individuals under 18, healthcare professionals, and patients with cognitive decline or sensory deficits that prevent informed consent. Healthcare professionals are excluded to prevent bias due to specialized knowledge of stroke, while individuals with severe cognitive decline or sensory deficits are excluded as these conditions may affect comprehension and response accuracy. Participants will be selected using a convenience criterion and will be surveyed to assess HL related to stroke and its prevention in the general population

Sample size

Since this study will be conducted on the general population, a large sample will be necessary to reduce the risk of selection bias.

The enrolment period will last approximately six months (Figure 1 and 2). A minimum sample size of 1,000 subjects is required, as a smaller sample may not adequately represent the desired differences (Martinez-Mesa et al., 2014). It is recommended that researchers use the largest sample size feasible, as larger samples provide more reliable estimates than smaller

ones (Tsang et al., 2017). The sample size was calculated using G*Power (version 3.1.9.7) based on Ronán Conroy's guidelines (Conroy, n.d.). For Italy's population of 58,990,000 (ISTAT, 2024) and Albania's estimated population of 2,800,000 (Fund, 2024), with a 3% margin of error, 95% confidence level, and 50% response distribution, 1,068 and 1,067 respondents are required, respectively. However, an approach based on margin of error alone is not sufficient to support the power of multivariate models and psychometric tests. Therefore, additional power analyses will be performed for the two key analytical objectives:

(a) Multivariable regression: Based on G*Power 3.1.9.7, assuming up to 10 predictors (sociodemographic and behavioral covariates) and an anticipated small-to-moderate effect size ($f^2 = 0.02$; equivalent to $\Delta R^2 = 0.02$), with $\alpha = 0.05$ and $1-\beta = 0.80$, a minimum of 485 participants per country would be required. Our planned sample of approximately 1,000 per country more than doubles this requirement, ensuring >95% power to detect small changes in explained variance in HL scores.

(b) Confirmatory factor analysis (CFA) and measurement invariance across languages: for CFA, simulation studies indicate that stable parameter estimation and adequate model fit evaluation require at least 10–15 participants per estimated parameter (Jackson, 2001). Given that our questionnaire include approximately 50–60 free parameters, a minimum of 500–600 cases per language group is recommended. Our planned sample of $\geq 1,000$ participants per country provides more than adequate power for both within-country CFA and multi-group invariance testing between the Italian and Albanian versions, exceeding the recommended minimum ratio of 10:1 (participants: parameters) for robust cross-cultural validation.

In summary, the final sample size is powered for detecting small-to-moderate associations in regression analyses and for stable estimation in multi-group CFA models assessing measurement equivalence across languages.

Procedures: data collection

The timelines of data collection and evolution of the EDUHELP project are depicted in Figure 1 and 2. Indeed, following the publication of the protocol, we will move on to phase one of data collection where the observational study of

stroke-related HL will be conducted on the two populations and then to the validation of the questionnaire.

Before being used with the Italian and Albanian populations, two nurses with expertise in stroke care and fluency in English and Italian will translate the scales from English into Italian and Albanian. An English teacher, fluent in both Albanian and Italian and with expertise in medical translation, will then back-translate the Italian and Albanian versions into English. The translator will be blinded to the original version of the scales. The back-translated versions will be reviewed by the scale developer to ensure that the original item content is accurately reflected in the Italian and Albanian versions. If necessary, modifications will be made.

Before the administration of the questionnaire, the items will be pre-tested on a small sample of 32 respondents. This sample size is required to achieve 80% power for the questionnaire in the future population to be surveyed (Perneger et al., 2015). This will allow the researcher to ensure that the original and translated items convey the same meaning and to verify that there is no confusion between the original and the translated questionnaire. The respondents will be asked to explain their understanding of each questionnaire item, assess its readability, and provide any suggestions they may have. During pre-testing, a cognitive interviewing approach will be applied with 32 participants (16 per country) purposively selected to represent diverse age, sex, and education profiles. The concurrent probing method will be used: after each item, interviewers will ask participants to verbalize their understanding, recall processes, and decision-making ("think-aloud" technique). Notes will be taken on comprehension difficulties, ambiguous wording, and culturally specific interpretations (Koskey, 2016).

Item modifications will be implemented only when at least 20% of participants report misunderstanding or unclear meaning. Revised items will be re-evaluated for clarity by two bilingual researchers (B, 2015; Beatty & Willis, 2007).

Content validity will be further assessed by an expert panel of six professionals (three per country) with expertise in stroke prevention, nursing, and public health. Each expert will independently rate item relevance and clarity on a 4-point Likert scale. The Content Validity

Index (CVI) will be calculated at the item (I-CVI) and scale (S-CVI/Ave) levels, with acceptable thresholds set at I-CVI ≥ 0.78 and S-CVI/Ave ≥ 0.90 , in line with Polit & Beck's recommendations (Polit et al., 2007).

The questionnaire will be predominantly administered face-to-face. Two interviewers (MY and FK) will ask questions of respondents in person, as it may be difficult for some, especially older adults, to understand the questions or use the internet.

Each section of the questionnaire will include written instructions on how to conduct the interview, making it easier for the participants and addressing potential sources of bias. To minimize selection bias, face-to-face interviews will be conducted first. The remaining subjects will be interviewed using an electronic web survey via Google Forms, a freely available platform for creating and distributing web-based questionnaires. Google Forms has been used in other primary prevention studies (Barakat et al., 2021; Hamzah et al., 2023). An automatic web URL for the questionnaire will be generated, and the link will be distributed via social networking sites and email. It will take approximately 15 minutes to complete this questionnaire.

The names in the questionnaires used for face-to-face interviews will be coded with an encoding key. These sensitive data will be securely archived

in a restricted location with no public access. Data collected through the electronic database will be anonymized by assigning a unique numeric code to each participant. These sensitive data will be stored in the electronic database by the principal investigator (GP).

Both open- and closed-ended questions will be included. General demographic information about the participants, such as gender, age, nationality, educational level, marital status, and occupation, will also be collected. As the sample is relatively large, missing data may occur.

Instruments

To assess stroke-related HL in the study participants, a combination of validated questionnaire will be employed to gather comprehensive data across several dimensions. The questionnaire used in this study include a socio-demographic questionnaire developed by the research team, the Stroke Knowledge Test (SKT), the Awareness of Stroke Symptoms and Risk Factors Questionnaire, and the Stroke Risk Factor Knowledge and Perception Questionnaire (SRFKPQ). These questionnaires are designed to measure participants' stroke-related knowledge, attitudes, and behaviors, thereby providing a clear understanding of the role of HL in stroke prevention and management. A summary of the questionnaire, including their constructs,

Table 2. Overview of the instruments used in the EDUHELP study, including construct, number of items, response format, scoring approach, and psychometric properties.

Instrument	Construct assessed	# Items	Response format	Scoring	Prior psychometrics	Planned reliability/ fit indices
Socio-demographic questionnaire (ad hoc)	Background information: age, sex, marital status, education, family history of stroke, etc.	16	Mix of open- and multiple-choice questions	Descriptive variables, categorical coding	Developed for this study	Internal consistency not applicable; descriptive summary only
Stroke Knowledge Test (SKT) (Sullivan & Dunton, 2004)	Knowledge of stroke signs, symptoms, risk factors, and response actions	15	Multiple-choice (single/multiple correct answers) and few open-ended	Total score = # correct answers (0–15)	Cronbach's $\alpha = 0.71$; test-retest $r = 0.83$	α and $\omega \geq 0.70$; CFA fit RMSEA ≤ 0.08 , SRMR ≤ 0.08
Awareness of Stroke Symptoms and Risk Factors Questionnaire (Ahmed et al., 2019).	Awareness of symptoms and risk factors; household and educational context	14	Closed-ended (yes/no/don't know) and categorical	Total knowledge score = # correct responses	Cronbach's $\alpha = 0.76$; validated in general population	α and $\omega \geq 0.70$; CFA for cross-cultural adaptation
Stroke Risk Factor Knowledge and Perception Questionnaire (SRFKPQ) (Madubuko, 2018).	Knowledge of risk factors, personal and family medical history, and lifestyle practices	27	5-point Likert (Strongly agree–Strongly disagree) and yes/no items	Mean item score and subscale totals	Cronbach's $\alpha = 0.79$; factor structure confirmed (3 factors)	α and $\omega \geq 0.70$; RMSEA ≤ 0.08 ; CFI ≥ 0.90 ; invariance across languages

number of items, response options, scoring procedures, previous psychometric evidence, and planned reliability and model fit indices, is presented in Table 2. Respondents will be asked to provide an email address or telephone number before beginning the questionnaire.

Socio-Demographic Characteristics Questionnaire: An ad hoc questionnaire developed by the research team will gather socio-demographic data, including variables such as age, sex, marital status, education, and health-related factors like family history of stroke. It will consist of 16 items, with items 1, 4, and 9 being open-ended questions, while the remaining items are multiple-choice questions.

The *SKT* (Sullivan & Dunton, 2004) will assess participants' knowledge of stroke signs, symptoms, risk factors, and behaviors related to prevention and treatment. It comprises multiple-choice questions with both single and multiple correct answers, as well as a few open-ended questions. It consists of 15 items, items 3 and 4 consist of open answers, in part also item 12, while the remaining part are multiple choice questions in part with only one correct answer or more than one.

The Awareness of stroke symptoms and risk factor Questionnaire (Ahmed et al., 2019) is a 14-item questionnaire that will assess knowledge of stroke symptoms and risk factors, in addition to gathering routine data on participants' personal characteristics, such as family education level and household structure. It is divided into two sections. In the first session, questions are asked to obtain information about the participants' knowledge of the signs, symptoms and risk factors of stroke. The second section will include routine questions about the individual's personal characteristics such as the educational level of the parents and with how many people they currently live with.

The SRFKPQ (Madubuko et al., 2018) is 27-item questionnaire that will assess knowledge of stroke symptoms and risk factors, in addition to gathering routine data on participants' personal characteristics, such as family education level and household structure. Consisting of 27 items, the SRFKPQ explores the participant's clinical condition, family medical history, and lifestyle.

Data analysis and statistics

Descriptive statistics (mean, standard deviation, median, interquartile range, and

frequencies) will be used to summarize socio-demographic, clinical, and scale data.

The primary outcome is the latent HL factor score derived from the confirmatory factor analysis (CFA) of the combined items from the Stroke Knowledge Test (SKT), Awareness of Stroke Symptoms and Risk Factors Questionnaire, and Stroke Risk Factor Knowledge and Perception Questionnaire (SRFKPQ). This latent HL construct represents overall stroke-related literacy.

Covariates included in multivariable analyses will be: age, sex, educational attainment, socioeconomic status, marital status, urban-rural residence, geographic region, and prior personal or family history of stroke. Lifestyle factors (smoking, physical activity, diet, and alcohol use) will also be considered as independent predictors.

Regression models will use multiple linear regression to estimate associations between covariates and the HL factor score. Model diagnostics will assess multicollinearity, residual normality, and heteroscedasticity. Statistical significance will be set at $p < 0.05$, with false discovery rate (FDR) correction applied for multiple hypothesis testing. To enhance population representativeness, post-stratification weights will be calculated based on national census data for age, sex, and region distributions in each country. Weighted and unweighted analyses will be compared to assess robustness. Sensitivity analyses will be performed excluding online-only respondents to evaluate potential differences between digital and face-to-face recruitment modes, and between urban and rural strata.

The multiple imputation (MI) procedure will include all variables used in the main regression analyses—namely, the outcome variable (latent HL factor score), sociodemographic covariates (age, sex, education, marital status, socioeconomic status, region, and urban-rural residence), and health-related predictors (lifestyle behaviors, prior stroke experience, and family history of stroke). In addition, auxiliary variables that are correlated with missingness (e.g., digital literacy, mode of administration, and self-rated health) will be included in the imputation model to improve accuracy and satisfy the missing-at-random (MAR) assumption.

We will perform multiple imputation by chained equations (MICE) with $m = 20$ datasets, using predictive mean matching for continuous

variables and logistic or ordinal logistic regression for categorical variables. Analyses of association (e.g., weighted multiple regression) will be based on pooled estimates following Rubin's rules (Burgess et al., 2013).

Imputation will be restricted to regression analyses; it will not be applied to CFA models with categorical indicators. Instead, CFA and measurement invariance analyses will handle missingness using the WLSMV estimator's pairwise approach for categorical data. Sensitivity analyses will compare results from complete-case and imputed datasets to verify robustness.

CFA will be conducted using Mplus Version 8 (Muthen & Muthen, 2010) to assess the dimensionality of each instrument and test measurement invariance across the Italian and Albanian samples. Given the categorical nature of the indicators, all CFAs (including multi-group invariance) will use a robust weighted least squares estimator (WLSMV, θ -parameterization) in Mplus v8. Missingness will be handled under WLSMV's default for categorical data; if item-level missingness exceeds ~5%, we will repeat analyses on multiply imputed datasets as a sensitivity analysis. Regression analyses will continue to use MI and FIML as previously stated, but FIML will not be used for CFA with categorical items. Goodness-of-fit will be evaluated using the following primary thresholds: CFI/TLI $\geq .95$ (acceptable $\geq .90$), RMSEA $\leq .06$ (acceptable $\leq .08$), SRMR $\leq .08$. Competing models will be compared with fit indices, parsimony, and theoretical coherence. We will evaluate configural, metric (loading), scalar (threshold) invariance for categorical indicators using the DIFFTEST option under WLSMV (Dubravka Svetina, 2019). Invariance decisions will follow $\Delta\text{CFI} \leq .010$ and $\Delta\text{RMSEA} \leq .015$ between nested models, alongside absolute fit indices. If full scalar invariance is not achieved, we will adopt partial invariance by freeing a minimal set of non-invariant loadings/thresholds based on modification indices and content. Latent mean comparisons will only be made at (partial) scalar invariance (Dubravka Svetina, 2019). Model comparisons for cross-language invariance will follow the $\Delta\text{CFI} \leq 0.010$ and $\Delta\text{RMSEA} \leq 0.015$ criteria (Dubravka Svetina, 2019). Weighted and unweighted analyses will be compared to evaluate representativeness. Sensitivity analyses will test the robustness of results by excluding online-only respondents and examining potential

mode (online vs. face-to-face) and regional effects. Because data collection will include both online and face-to-face administration, potential mode effects—differences in responses attributable to the survey mode rather than true population differences—will be explicitly assessed. First, descriptive comparisons will be conducted between respondents recruited online and those surveyed face-to-face across key sociodemographic variables (age, sex, education, region, urban-rural residence) to evaluate selection differences.

Next, we will test for measurement equivalence across modes using a multi-group confirmatory factor analysis (CFA) with mode (online vs. face-to-face) as the grouping variable. Configural, metric, and scalar invariance will be examined sequentially under the WLSMV estimator for categorical indicators, applying $\Delta\text{CFI} \leq .010$ and $\Delta\text{RMSEA} \leq .015$ as invariance thresholds. If partial invariance is achieved, latent means will be compared to identify systematic score differences by mode.

Additionally, as a robustness check, we will fit a MIMIC (Multiple Indicators–Multiple Causes) model, adding a binary mode covariate (0 = face-to-face, 1 = online) to test for direct effects of mode on individual items while controlling for the latent HL factor and sociodemographic covariates (Tekwe et al., 2014). Significant mode effects ($p < .05$ after FDR correction) will be reported and, if substantial, corrected using multiple-group or MIMIC-adjusted estimates in the main analyses. Weighted regression analyses will also be repeated within each mode subgroup to assess whether associations between covariates and HL differ across collection modes.

Analyses will be performed using SPSS v.28 for descriptive and regression models, and Mplus v.8 (Muthen & Muthen, 2010) for CFA and structural equation modeling.

Measurement model

We conceptualize stroke-related HL as a latent construct reflected by items covering three knowledge/action domains: (i) recognition of stroke symptoms; (ii) knowledge of risk factors; and (iii) intended action/response in time-critical situations. Items contributing to these domains are drawn from the Stroke Knowledge Test (SKT), the Awareness of Stroke Symptoms and Risk Factors Questionnaire, and the Stroke Risk Factor Knowledge and Perception Questionnaire

(SRFKPQ). Open-ended items will be coded by two independent raters into dichotomous or ordered categories (0 = incorrect/omitted; 1 = partially correct; 2 = fully correct where applicable); disagreements will be resolved by consensus (κ reported).

We will test three theoretically-plausible structures in a confirmatory framework: a) Unidimensional model: all items load on a single HL factor (g-HL); b) Multidimensional correlated-factors model: three first-order factors—Symptoms, Risk Factors, Action/Response—allowed to correlate; c) Bifactor model: a general HL factor (g-HL) plus the three orthogonal domain-specific factors capturing residual domain variance (van Zyl & Ten Klooster, 2021).

Model comparison will be based on fit indices and interpretability. If the bifactor model is retained, we will report ω_H (omega-hierarchical) for the general factor and explained common variance to quantify the prominence of g-HL (Flora, 2022). The integration of items from different questionnaires will be carried out using two methodologies, as the items are harmonized into categorical indicators (binary/ordinal) and mapped to the above domains regardless of the source instrument. To address potential method variance due to instrument origin or item stems, we will (a) use local residual correlations only when strongly warranted by modification indices and content (Bandalos, 2021), or (b) add instrument method factors (orthogonal to substantive factors) as a sensitivity analysis (Ellis, 2017). No parcels will be used; all items are modeled directly to preserve diagnostic information.

Depending on the retained structure, the primary outcome will be (a) the g-HL factor score (unidimensional/bifactor), or (b) a composite latent HL score derived from the correlated-factors solution (and, secondarily, domain-specific scores). This replaces the previous generic description of a single CFA-derived HL score and aligns scoring to the empirically supported structure.

Ethical consideration

This study was reviewed and approved by the Ethics Committee of the Catholic University “Our Lady of Good Counsel,” Tirana, Albania (Approval No. Pr.362/2021). The protocol adheres to the principles of the Declaration of Helsinki

(2013 revision) and the European Union General Data Protection Regulation (GDPR 2016/679).

In accordance with the EU General Data Protection Regulation (GDPR 2016/679) and national privacy laws in Italy and Albania, data processing will be based on explicit informed consent obtained from all participants prior to participation (Article 6(1)(a), GDPR).

Each participant’s identifying information (name, contact details) will be stored separately from survey responses and linked only via a randomly generated numeric code. The linkage key will be securely stored in an encrypted, access-restricted file and will be destroyed within six months after data collection is completed. De-identified data will be retained for five years for secondary analyses and quality assurance, after which they will be permanently deleted.

The data controller for the study is the Catholic University “Our Lady of Good Counsel,” Tirana, Albania, represented by the Principal Investigator (GP), who can be contacted for any data protection-related inquiries at his institutional email address.

All data transfers between research partners will occur through encrypted channels, and only aggregated, anonymized data will be shared for analysis.

Expected Results

We anticipate observing heterogeneity in stroke-related HL across and within countries, with lower average HL in Albania than in Italy, consistent with differences in health-system resources, health information access, and prior public health campaigns described in the introduction.

Primary outcomes (population survey)

Descriptive analyses will likely show right-skewed distributions of HL-related knowledge, with gaps in the recognition of early stroke symptoms and time-critical actions, and incomplete knowledge of modifiable risk factors (e.g., hypertension, atrial fibrillation, smoking, physical inactivity). We expect faster intended response behaviors (e.g., calling emergency services) to be more frequently reported in Italy than in Albania. Urban residence and previous exposure to stroke (self or family) are expected to correlate with higher knowledge scores.

Predictors of HL

In multivariable linear regression, we expect lower HL scores to be independently associated with older age, lower educational attainment, lower socioeconomic position, rural residence, and absence of prior stroke exposure, whereas higher HL should be associated with younger age, higher education, urban residence, and prior exposure to stroke. We also anticipate health-behavior correlates: higher HL co-occurring with more frequent physical activity, healthier diet patterns, nonsmoking status, and lower hazardous alcohol intake on the SRFKPQ lifestyle items. Effect directions should be stable across countries, though magnitudes may differ.

Secondary outcomes: Instrument performance (validation phase)

For the SKT, Awareness of Stroke Symptoms and Risk Factors Questionnaire, and SRFKPQ, we expect acceptable internal consistency (Cronbach's α and McDonald's $\omega \geq 0.70$) and adequate CFA fit under the planned estimation (e.g., RMSEA ≤ 0.08 ; SRMR ≤ 0.08), supporting linguistic and cultural appropriateness of the Italian and Albanian versions. Item performance is expected to reveal a small subset of easier items with ceiling effects (basic symptom recognition) and several discriminating items (time-to-action, atrial fibrillation, and lifestyle risk factors), aligning with the knowledge gaps described above. Where individual items show weak loadings or misfit, minor wording refinements will be proposed without altering the substantive constructs.

Discussion

Our multidimensional survey is based on a recent European study (Sorensen & Bredahl Kristensen, 2023), which states that Europe has a large and fragmented picture of cardiovascular disease mortality and incidence, specifically noting that inequalities in cardiovascular disease mortality are massive in Central and Eastern Europe. Hence, our survey includes two countries from this region, Italy and Albania. A potential limitation of this study is its convenience sample which may not be representative of the population.

However, cognitive survey of the state of knowledge of lifestyles and preventive behaviors

implemented by these two populations could make aware of the public health of the two nations, defining new pathways to make aware and implementable primary prevention pathways on stroke. Public health interventions, particularly on primary prevention, has shown great effectiveness in increasing population awareness of symptoms, which means fewer hospital delays, morbidity, and mortality (Mszar et al., 2020). In addition, these studies aim to show how the burden of stroke can be reduced by identifying and reducing stroke risk factors. However, only a few studies have demonstrated a causal relationship between HL and health outcomes in cardiovascular disease (Albus, 2018; Visscher et al., 2018; Walters et al., 2020). These studies could identify key predictors of stroke, for new preventive health policies in Central and Eastern European countries.

The cognitive survey expressed as a goal in the first study will bring new data and help future research create appropriate health interventions. By recruiting participants from the general population of all ages, our study will reflect the actual situation of stroke knowledge. Regarding the recognition of predictors in these two countries, it is crucial, as expressed by Kur et al. (Kaur et al., 2022), as it allows focusing precisely on the population under investigation, facilitating the acquisition of predictors of poor HL and the right notions about stroke, which are fundamental criteria for primary prevention in public health. Studying stroke in a particular area is important for several reasons. First, it helps identify knowledge, causes, gaps, symptoms, and outcomes in a particular region (Han & Jang, 2021). To our knowledge, this will be the first study in Albania that attempts to assess HL; unlike Italy, where a survey on general elements of knowledge related to stroke has already been investigated but goes back 9 years and investigates knowledge only in adults (Baldereschi et al., 2015). The proposed research will examine HL as a cause of disability and death. We believe that it is critical to study the population of a particular region to learn about its culture and education level, which can help identify factors that promote HL. For this reason, we will also include questions about education level, socioeconomic status, HL vascular risk factors, and treatment options, which can expand our ability to explore additional factors that might be associated with a lack of understanding of stroke.

Regarding the second validation study of

the cognitive survey instrument, it would be important to uniquely investigate knowledge and risk factors for stroke. In Italy, we have an instrument that investigates the readiness for stroke identification by the population (Denti et al., 2015), but there are no questionnaire that give a picture of knowledge related to stroke prevention. As for the Albanian population to our knowledge, it does not have questionnaire that investigate knowledge about stroke to prevent it. Finally, providing questionnaire such as questionnaires to target the level of stroke knowledge (Hou et al., 2017) can make health professionals aware of the population to be indoctrinated, with the goal of targeting the right educational interventions in the target population.

In the literature, several guidelines are provided on how to structure primary prevention interventions in the population (Feigin et al., 2016; Sullivan et al., 2008; Yan et al., 2016); but in our case, given the cognitive survey and psychometric inquiry, we may be able to develop a usable program specific to the populations under investigation. Indeed, in a recent scoping review (Movsisyan et al., 2021), we define how important it is to investigate the knowledge levels of a population about a particular object of study, so as to make an intervention adaptable to the entire population previously investigated. Indeed, this is precisely the motivation for developing the program at the end of the two antecedent studies. It is extremely engaging to link the three surveys that could develop new interventions, tailored to the needs that emerged from the two populations.

Implications

Collectively, these results are expected to: map HL deficits most strongly associated with suboptimal intended response and preventable risk profiles; and identify high-risk subgroups (by age, education, residence, and prior exposure) for tailored messaging; and support the feasibility and reliability of the adapted questionnaire for routine population surveillance and for evaluating future educational interventions in both countries.

Conclusions

These studies provide researchers with a solid foundation to revise and adapt existing

interventions, aligning them more closely with the specific needs of diverse populations. By doing so, interventions become more usable, equitable, and scalable across varying levels of public health need. As the most comprehensive domain of public health, primary prevention plays a critical role in averting diseases with significant socioeconomic consequences. Effective primary prevention strategies can help reduce the incidence of conditions such as stroke, ultimately mitigating the long-term health and social burdens associated with disability.

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Exploring the Impact of a Nurse-Led Narrative Interview on Newly Diagnosed Hematologic Patients: A Holistic Qualitative Single-Case Study Protocol

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Abstract

Objectives. A diagnosis of hematologic malignancy represents a major biographical disruption, affecting emotional, relational, and existential dimensions of patients’ lives. While biomedical care predominates, patients’ lived experiences during the early diagnostic phase remain insufficiently explored. This study protocol aims to investigate whether nurse-led narrative interviews conducted within the first month after diagnosis can strengthen the therapeutic relationship, enhance trust, support emotional expression, and sustain patients’ sense of identity and agency.

Trial Design. This study adopts a qualitative, holistic single-case study design, grounded in a constructivist-existentialist epistemological framework. An exploratory approach is used to generate in-depth, context-sensitive insights and inform future larger-scale qualitative research.

Participants and Settings. The study will be conducted in the onco-hematology department of a tertiary hospital in Northern

Italy. One adult patient (≥ 18 years) with a first diagnosis of hematologic malignancy within the previous 30 days will be recruited through purposive sampling. A primary caregiver will also be involved to provide a complementary perspective. Inclusion criteria include linguistic competence in Italian and clinical stability to provide informed consent.

Interventions. The intervention consists of two nurse-led narrative interviews conducted approximately 15 days apart. Interviews will be guided by open-ended questions and conducted by a trained nurse using attentive, empathetic listening. Additional data sources include reflective writing by both the patient and the nurse following each interview, and a semi-structured interview with the caregiver after the second narrative interview.

Primary and Secondary Outcomes. Primary outcomes focus on qualitative indicators of meaning-making, emotional expression, therapeutic alliance, and perceived support as expressed through narratives and reflections. Secondary outcomes include triangulated insights from nurse, caregiver, and researcher perspectives. Data will be analyzed using Reflexive Thematic Analysis, with methodological triangulation to enhance rigor and credibility.

Conclusions. This protocol will describe a holistic qualitative single-case study exploring the impact of nurse-led narrative interventions on relational and meaning-making processes in patients newly diagnosed with hematologic malignancies, providing a foundation for future person-centered research and clinical integration.

Keywords: Hematologic Malignancy, Holistic Qualitative Case Study, Narrative Interview, Narrative Nursing, Nurse-led Intervention

Introduction

A diagnosis of a hematologic disease represents not only a medical event but also a profoundly transformative life experience, reshaping a person's physical health, psychological wellbeing, social identity, and existential outlook (Lekarakou et al., 2024). From the moment of diagnosis, patients face a new and often unsettling reality, as their familiar sense of self and daily routines are disrupted by medical interventions, hospital visits, and persistent uncertainty. The timing of this disclosure – whether occurring abruptly during acute illness or more gradually following extended diagnostic investigations – can significantly influence patients' emotional responses, coping strategies, and capacity to integrate the diagnosis into their life narrative

(Gregorio et al., 2024; Winestone et al., 2024). Treatment regimens such as chemotherapy, immunotherapy, or stem cell transplantation often extend over months or years, requiring patients to repeatedly adapt to bodily changes and renegotiate their self-identity in the context of illness-related limitations and hopes for recovery (Lekarakou et al., 2024). These challenges profoundly affect family dynamics, work life, and relationships, with loved ones also coping with emotional and practical demands of living with a chronic, life-threatening condition (Shah et al., 2024).

The onset of a hematologic disease often constitutes a profound biographical disruption, a concept introduced by Bury (1982) to describe the way chronic illness can fracture the continuity of one's life narrative, challenging personal identity,

social roles, and future plans. This disruption shifts existence from the previously taken-for-granted to one redefined by uncertainty and dependence (Bury, 1982). While biomedical management remains fundamental to disease control and treatment, an exclusive emphasis on survival outcomes tends to marginalize these subjective, deeply human dimensions of illness. Patients' lived experiences risk being reduced to numerical indicators such as blood counts or remission rates (Weiss & Johnson-Koenke, 2023), which fail to capture the existential complexity of living with a hematologic disease.

To address this gap, narrative medicine and narrative nursing have emerged as vital frameworks for re-centering the patient's voice and fostering a more holistic understanding of health, suffering, and healing (Egnew, 2018; Weiss & Johnson-Koenke, 2023). In this context, holistic medicine emphasizes care of the whole person – physical, psychological, social, and spiritual – using approaches such as psychosocial support and integrative therapies to complement biomedical treatment and improve quality of life in cancer patients (Wei et al., 2024).

Narrative medicine encourages clinicians to listen actively and empathetically, recognizing patient stories as essential sources of insight into fears, hopes, and coping strategies (De Vincentis et al., 2018; Egnew, 2018; Slocum et al., 2017; Zocher et al., 2020). This approach fosters empathy and enhances clinical decision-making by aligning care with what matters most to patients (Paul et al., 2024). Building on these principles, narrative nursing translates narrative medicine into everyday clinical practice, emphasizing attentive listening, presence, and meaning co-construction through dialogue. By embracing patients' narratives, nurses respond more sensitively to emotional and psychosocial needs often hidden behind biomedical data (Paul et al., 2024; Rivest et al., 2023).

In clinical contexts, narrative nursing has been applied in oncology, palliative care, and chronic illness management to strengthen therapeutic relationships, improve communication, and facilitate patient meaning-making (Paul et al., 2024). According to Bert (2007), these applications demonstrate its potential to support person-centered care and address the existential challenges often experienced in serious illness (Bert, 2007).

Within this framework, the narrative interview

emerges as a structured, dialogic expression of the principles underpinning both narrative medicine and narrative nursing. Rooted in the ethos of relational care and meaning-making, the narrative interview provides patients with a dedicated space to share their illness stories in their own words. Especially when introduced early in the cancer care pathway, it serves not only as a research method but also as a therapeutic intervention. Through open-ended and reflective dialogue, patients are encouraged to express fears, hopes, and coping strategies, fostering trust and generating insights that often remain hidden in structured clinical encounters (Turner et al., 2024). This co-constructed exchange values patients as experts of their own experience and strengthens the therapeutic alliance through authentic listening and recognition. The emotional relief and validation that emerge from being heard contribute to a deeper sense of connection and psychological integration (Abdallah et al., 2022; Ghodraty-Jabloo et al., 2016; Herrmann et al., 2020; LeBlanc et al., 2017; Nissim et al., 2013; Tsatsou et al., 2021). Moreover, narrative interviews support patients in reframing the meaning of their illness and maintaining a sense of identity and biographical continuity, even in the face of disruption (Artioli et al., 2024). Importantly, narrative approaches also benefit caregivers by validating their experiences, reducing feelings of isolation, and fostering more open communication with both patients and healthcare professionals. By engaging caregivers in narrative processes, studies have shown improvements in relational understanding and caregiver coping, which may ultimately enhance the overall quality of family-centered cancer care (Tuck et al., 2025).

Complementing the narrative interview, reflective writing offers a parallel opportunity for introspection (Slocum et al., 2017). While the interview facilitates meaning through relational dialogue, writing provides a private, structured space to process emotions, clarify values, and foster a sense of agency and coherence (Slocum et al., 2017). These benefits extend beyond patients: reflective writing also supports clinicians by helping them process their emotional responses, reinforce empathy, and maintain resilience in emotionally complex settings such as hematologic care (Bracken, 2021). Taken together, narrative interviews and reflective writing contribute to a more humanized, relational approach to care – one

that honors the lived experience of illness and fosters connection, trust, and meaning for both patients and professionals.

Recent evidence highlights the feasibility and value of nurse-led narrative interviews shortly after a cancer diagnosis (Wen et al., 2024; Zheng, 2024). These structured conversations have been shown to catalyze patient self-awareness, emotional adaptation, and engagement in care (Artioli et al., 2024). In the context of hematologic malignancies – particularly leukemia – where treatment is prolonged, complex, and emotionally demanding, embedding narrative practices within nursing care could enrich therapeutic relationships and promote compassionate, ethically grounded practice (Anderson et al., 2016; Groleau et al., 2006). Despite their potential, however, nurse-led narrative interviews remain underutilized in hematologic care, and little is known about their concrete impact on patient adaptation and meaning-making when implemented early in the care trajectory. This protocol addresses this gap by exploring how such an interview may function as a meaningful, holistic intervention – capable of strengthening the therapeutic alliance, enhancing patients' sense of agency, and promoting emotionally responsive, person-centered care during one of the most vulnerable phases of the cancer journey.

Objective

Accordingly, this study protocol aims to explore how a nurse-led narrative interview, conducted within the first 30 days following a hematologic diagnosis, can serve as a meaningful source of support for patients. Specifically, it will examine whether and how this narrative approach strengthens the therapeutic relationship, fosters trust and mutual understanding, promotes emotional relief, and enhances patients' sense of agency and resilience during their treatment journey.

Methods

Study Design

This study will employ a holistic qualitative single-case study methodology, suitable for in-depth examination of complex phenomena in real-world settings (Brogan et al., 2019). Case

study research is particularly effective when the boundaries between the phenomenon and its context are blurred. Given the exploratory nature of this investigation, an exploratory case study design will be adopted to generate hypotheses for future larger-scale studies (Yin, 2017). The holistic focus will allow examination of the case in its entirety, preserving complexity while understanding dynamic processes such as illness experiences and relational dynamics (Yin, 2017). The study will be rooted in a constructivist-existentialist epistemological framework, which considers knowledge as co-created through lived experience, reflection, and interpersonal engagement (Sibbald et al., 2021).

The central research question guiding the study will be: What are the impacts and perceived effects, as viewed from multiple perspectives, of two nurse-led narrative interviews conducted fifteen days apart with a newly diagnosed onco-hematologic patient? Four perspectives will be integrated: (a) the researcher's interpretation; (b) the patient's personal experience; (c) the nurse interviewer's viewpoint; and (d) the caregiver's perspective. This multidimensional approach aims to generate rich theoretical insights that can inform future research and advance nursing practice in complex care trajectories.

Participants and Setting

The study will be carried out in the onco-hematology department of a tertiary hospital in Northern Italy, characterized by complex treatment regimens and emotionally intense care pathways. Participants will be recruited via purposive sampling, including a single adult patient (≥ 18 years) with a first hematologic malignancy diagnosis within 30 days, explicitly excluding patients with solid tumors. Inclusion criteria will include proficiency in Italian, cognitive and clinical stability to consent, and willingness to engage in two narrative interviews conducted approximately two weeks apart. Exclusion criteria will include severe cognitive impairment, inability to provide informed consent, unstable clinical condition precluding participation, and withdrawal or refusal of consent.

Eligible patients will be identified by a clinical nurse collaborating with the research team, who will introduce the study but not conduct eligibility screening, ensuring unbiased selection. Informed consent will be obtained

before any data collection, emphasizing voluntary participation.

Study Procedure and Methodological Framework

The research will unfold in three interconnected phases, consistent with Yin's (2017) qualitative case study framework (Yin, 2017) and guided by a constructivist paradigm (Sibbald et al., 2021) that values participants' subjective experiences and the co-construction of meaning through narratives and reflexivity. Table 1 presents the data collection timeline.

Table 1. Timeline data collection.

Assessment	Day 0	T0 (~30 days)	T1 (31-45 days)	Post T1
Diagnosis	X			
Narrative interview		X	X	
Reflective writing for patients		X	X	
Reflective writing for interviewers				X
Caregiver interview				X
Focus group (ward team)				X

Phase 1: Case Analysis – Data Collection, Thematic Analysis, and Meaning Evolution

Data Collection

Data will derive from two narrative interviews conducted with the same patient, spaced approximately 15 days apart. Narrative interviewing, used as a relational technique, facilitates eliciting rich life and illness stories (Artioli et al., 2019). Interviews will take place face-to-face in a confidential setting within the onco-hematology department, approximately 30 to 45 days post-diagnosis. During each session, the nurse will pose a small set of open-ended questions, practicing attentive, empathetic listening. Importantly, the nurse conducting interviews will not perform patient selection; recruitment will be conducted independently by the research team, ensuring unbiased enrollment. The nurse will receive targeted training to develop advanced narrative interviewing skills (Artioli et al., 2024).

Table 2 and table 3 show the guide of Narrative Interview in T0 and T1. Interviews will be audio-recorded, anonymized, and transcribed

verbatim, with sociodemographic data collected at the end.

Table 2. Narrative Interview – T0.

Narrative Interview – T0
Participant Information: • Code, Age, Gender, Profession • Time since diagnosis communication • Interview location and duration • Interviewer's name
Example opening: Would you feel comfortable describing how the communication of your diagnosis took place? (Try to understand where the conversation happened, the communication style used, what was said, and who was present.)
1. Communication of the diagnosis as a source of stress These questions are intended as a guide to begin a conversation about how the communication of a cancer diagnosis relates to the patient's feelings of distress and personal difficulties. Example: "Could you tell me how you are feeling right now?"
2. The patient's adaptation to the illness These questions can help you understand whether the person has changed their internal or external coping strategies for dealing with the illness. Example: "What emotions and sensations are you experiencing at this moment?"
3. The impact of the illness on life and relationships These questions help to understand how, and if, the person's life has changed since the last meeting and whether there have been changes in specific areas: physical well-being (symptoms related to the disease and/or treatment), psychological well-being (emotional and cognitive aspects), social well-being (social relationships and family life), and finally spirituality, religion, or personal beliefs. Example: "Could you describe how you think your life has changed so far?"
Example closing question: "We are almost finished for today – is there anything else that comes to mind that you would like to add? Would you like to meet again in about fifteen days?"
Example closing: "Thank you very much for your time and willingness to share. I'd like to close the interview now, but may I contact you again if, after reviewing what we've discussed, there are any points that would be helpful to explore further?"

Data Analysis

Data will be analyzed using Braun and Clarke's Reflexive Thematic Analysis (Braun & Clarke, 2019, 2021), following six iterative steps: familiarization, coding, theme development, review, definition, and reporting. Two researchers will independently code transcripts; discrepancies will be resolved through discussion with a third researcher. Reflexive practices will acknowledge interpretive subjectivity and minimize bias (Braun & Clarke, 2024; Sibbald et al., 2021).

Table 3. Narrative Interview – T0.

Narrative Interview – T1
Participant Information: • Code, Age, Gender, Profession • Time since diagnosis communication • Interview location and duration • Interviewer's name
Example opening: <i>"Thank you for being here again. How have you been feeling since we last met?"</i>
1. Communication of the diagnosis as a source of stress These questions are intended to highlight whether there have been any changes related to feelings of distress or personal difficulties connected to how the diagnosis was communicated. Example: <i>"As of today, how do you feel about the way your diagnosis was communicated?"</i> (Explore whether anything has changed since the first interview in terms of thoughts, emotions, worries, or expectations.)
2. The patient's adaptation to the illness These questions can help you understand whether the person has changed their internal or external coping strategies for dealing with the illness. Example: <i>"As of today, can you tell me how you are coping with your illness? Do you feel your life has changed? If so, in what ways?"</i> (Explore any changes in thoughts and emotions regarding how they manage the illness and adapt to it.)
3. The impact of the illness on life and relationships These questions help to understand how, and if, the person's life has changed since the last meeting and whether there have been changes in specific areas: physical well-being (symptoms related to the disease and/or treatment), psychological well-being (emotional and cognitive aspects), social well-being (social relationships and family life), and finally spirituality, religion, or personal beliefs. Example: <i>"In your opinion, what changes have occurred in your life?" "What changes, if any, have there been in your relationships with family and friends?"</i> (Physical aspects, concerns, social and family relationships, self-image, social roles, work, etc.)
Example Closing: <i>"Thank you again. Is there anything else you'd like to add?"</i>

Meaning Evolution

This step will identify and describe shifts in meaning across the two interviews. Researchers will closely examine changes in language, emotional tone, and perceptions to track evolving internal narratives over time. Attention will be paid to new metaphors, shifts in temporal orientation, and modifications in self-positioning. These elements, triangulated with nurse and caregiver reflections, provide evidence of evolving internal narratives without imposing pre-established interpretative models, preserving participant voice and idiographic understanding (Artioli et al., 2024; Audulv et al., 2023).

Phase 2: Integrative Analysis of Multiple Perspectives

To capture the phenomenon's complexity, four analytical units will be examined collectively (Yin, 2017). Table 4 presents the data collection guides, while the conceptual framework is illustrated in Figure 1.

Table 4. Integrative Analysis of Multiple Perspectives.

Researcher Perspective: Focus Group – Care Team
Guiding questions: • What aspects of the patient's life did this interview help you understand? • What impact do you think these interviews had on the patient and caregiver? • Did these interviews have any effect on how you provide care? • Is there anything else you would like to add?
Patient Perspective: Reflective Writing
Instructions: Find a quiet place where you can be undisturbed for 15–20 minutes. Sit in silence, focus on yourself, and write freely or record your reflections using these guiding questions: • How did you feel during the interview? • What did the interview bring up for you? Were there moments you appreciated or found challenging? • Do you feel you have any needs that might help you experience future interviews better? • Is there anything else you would like to share?
Nurse Interviewer Perspective: Reflective Writing
Instructions: Find a quiet place where you can be undisturbed for 15–20 minutes. Reflect on your experience as the interviewer and write freely using these guiding questions: • How did you feel during the interview(s)? • What differences did you notice between this narrative interview and interviews you conduct in routine practice? • What aspects of the patient's life did this interview allow you to better understand? • Were there any difficult moments? • What are the strengths of this type of interview? • What would you change about the process and why?
Caregiver Perspective: Caregiver Interview
Instructions for the interviewer: Before starting, explain the aim, obtain consent, and create a trusting, open atmosphere. Use these questions as a guide. Example of questions after the interview with the family member: • What reactions and feelings did your family member have during the interview? • How did you feel during and after the interview? • What do you think about the usefulness of this interview for the patient? • Did you notice any difficulties for the patient after the interview? • Do you feel this interview could be helpful for you as a caregiver? • Did you experience any difficulties related to this interview?
Example of closing quote: <i>"Is there anything else you'd like to add?" Thank them and ask for permission to follow up if needed.</i>

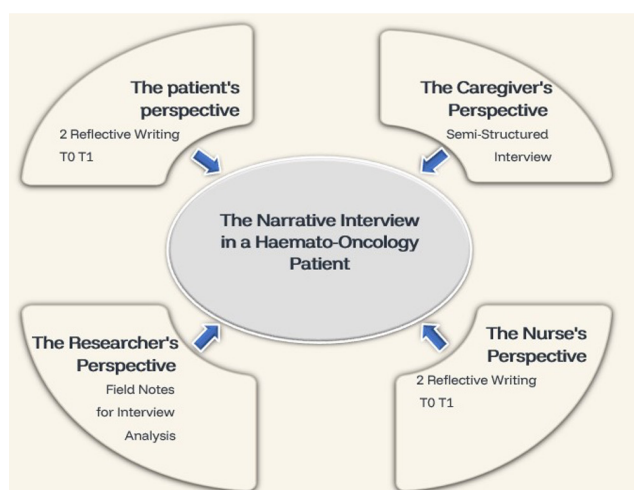


Figure 1. Conceptual framework.

Researcher Perspective

Researchers will maintain detailed field notes during analysis, focusing on nuances and divergences between the two interview timepoints. These notes will facilitate team discussions and will refine conceptual understanding termed the “researcher perspective”, which will enhance analytic rigor and depth.

Patient Perspective

Following each narrative interview, the patient will engage in structured reflective writing exercises (Slocum et al., 2017) aimed at deepening introspection and further articulating her experience. Consistent prompts will enable comparative analysis over time, with these narratives analyzed alongside interview transcripts to enrich understanding.

Nurse Interviewer Perspective

Mirroring the patient’s reflections, the nurse will complete structured reflective writings post-interview, commenting on the interview process, relational dynamics, and perceived data quality. While the nurse serves both as interviewer and author of these reflections, this dual role is methodologically intentional and justified. Nurse’s reflections will be analyzed alongside three additional perspectives – the patient, the caregiver, and the research team – ensuring triangulation and providing a counterbalance to any potential self-referential bias. The reflective writings of the nurse may also contribute to reflexivity, allowing the research team to critically consider how relational dynamics and

interviewer choices may influence the data. During team discussions and collaborative triangulation, any interpretive biases introduced by the nurse will be identified and discussed, enhancing analytic rigor. In this way, the nurse’s dual role strengthens the study by deepening contextual understanding, supporting nuanced interpretations, and capturing relational subtleties that would be inaccessible through patient or caregiver data alone.

Caregiver Perspective

To broaden contextual insights, a semi-structured interview will be conducted with the patient’s primary caregiver soon after the second patient interview. This approach will balance predefined questions with openness to emergent themes (Adeoye-Olatunde & Olenik, 2021)

Phase 3: Data Triangulation

Data triangulation, a cornerstone of robust case study research, will be employed to enhance validity by integrating multiple qualitative data sources. This strategy will allow cross-verification of findings, mitigate biases associated with single sources, and support a richer, multifaceted interpretation of the case’s complexities (Schlunegger et al., 2024). By synthesizing narrative intervention, reflective writings, and field notes, the study will achieve a holistic, coherent representation of the phenomenon grounded in diverse evidentiary strands, thereby reinforcing the credibility and depth of the interpretative framework (Yin, 2017).

Research Rigor

To ensure robust methodological rigor, this study will follow established principles of trustworthiness in qualitative research (Gaikwad, 2017; Houghton et al., 2013). Credibility is reinforced through triangulation of multiple data sources – including patient interviews, reflective writings, caregiver perspectives, focus group insights, and field notes – to build a rich, evidence-based understanding. Peer debriefing by an external expert will critically review coding and thematic analysis, adding validation. Dependability will be supported by a transparent audit trail documenting methodological choices. Confirmability will be ensured via

systematic reflexivity: the research team will maintain journals to monitor assumptions and biases and engages in open dialogue to confront preconceptions. Researchers will clearly communicate their roles to participants, promoting trust and situating the study within the real-world ward context. The team's combined expertise in nursing, clinical practice, qualitative research, and organizational psychology will ensure sensitive and informed observations. Direct observation by experienced nurses will minimize misinterpretation of patient and family behaviors. Transferability will be enhanced through rich contextual descriptions, allowing other practitioners and researchers to assess applicability. Together, these strategies ensure credible, transparent, and meaningful study results (Gaikwad, 2017; Houghton et al., 2013).

Ethical Considerations

The study will adhere to the approved protocol and the Declaration of Helsinki. Participants will receive clear explanations and provide written informed consent, covering interviews, reflective writings, sociodemographic data, and research use of all data. Withdrawal will be permitted at any time. Ethical approval was obtained from the Ethics Committee of Area Emilia Nord, Piacenza (protocol 2024/0105011 of 30/09/2024).

Discussion

This protocol builds directly upon the pilot feasibility study conducted by Artioli et al. (2024), which examined the impact and acceptability of a nurse-led Narrative Intervention for patients recently diagnosed with cancer (Artioli et al., 2024). The primary aim of that preliminary investigation was to explore how a nurse-facilitated Narrative Intervention could support patients in coping with their illness at the critical juncture of initial oncologic diagnosis. Findings highlighted multiple benefits: the intervention facilitated patient expression of complex emotions and the reframing of their illness experience, enabled healthcare professionals to gain a richer understanding of the patient's narrative and individual needs, and provided caregivers with valuable perspectives on the patient's emotional journey.

However, the pilot's limited sample restricted exploration of intervention variability across diverse patient contexts and did not

integrate caregiver and multidisciplinary team perspectives systematically. The present study protocol addresses these gaps by explicitly including caregiver input, employing triangulation across multiple viewpoints, and refining methodological strategies to better capture the relational and contextual dynamics of narrative practice in hematology care, thereby generating novel insights into the early-phase use of nurse-led narrative interviews.

Extant literature corroborates the effectiveness of Narrative Intervention across various clinical settings, including oncology, palliative care, and chronic disease management (Tuck et al., 2025; Zhang et al., 2024).

To further strengthen the international context of this work, we have integrated recent studies, including Tuck et al. (2025), Winestone et al. (2024), and Paul et al. (2024), demonstrating the relevance and impact of narrative interventions across diverse healthcare systems (Winestone et al., 2024; Paul et al., 2024; Tuck et al., 2025).

Seminal works by Artioli et al. (2019) and Egnew (2018) demonstrated that Narrative Intervention can facilitate patients' meaning-making processes, promote reframing of suffering, and enhance patient-provider communication (Egnew, 2018; Artioli et al., 2019). Similarly, De Vincentis et al. (2018) underscored the capacity of narrative approaches to help patients articulate nuanced emotions that might otherwise remain unvoiced (De Vincentis et al., 2018). More recent evidence by Tuck et al. (2025) reinforces these foundations, showing that Narrative Intervention combined with creative modalities uncovers the lived experiences of cancer patients and their families, revealing psychosocial, spiritual, and economic challenges often concealed in routine clinical encounters (Tuck et al., 2025). Collectively, this evidence substantiates the potential of narrative methodologies to reveal otherwise hidden dimensions of patient experience and guide culturally sensitive, comprehensive care.

Adopting a holistic qualitative single-case study design, this updated protocol aims to elucidate the impact of Narrative Intervention from multiple interconnected perspectives: the patient, the interviewing nurse, the primary caregiver, and the involved ward professionals. Maintaining the Narrative Intervention structure and timing established in the 2024 pilot – two interviews conducted 30 to 45 days post-

diagnosis and repeated 15 days later – the study seeks to generate more robust evidence on how narrative approaches support meaning-making, psychological adaptation, and relational care in hematologic.

Anticipated outcomes include a nuanced understanding of how Narrative Intervention facilitates patient emotional articulation and illness awareness during the early adjustment phase, enriches caregivers' insight into coping mechanisms, and fosters reflective practice among healthcare professionals – potentially enhancing the team's empathic and compassionate care delivery. Importantly, this study transcends mere sample expansion, situating the Narrative Intervention within a complex, real-world clinical environment that acknowledges narrative work as inherently relational, holistic, and co-constructed.

The broader significance of this research lies in its contribution to the evidence base supporting narrative nursing as a feasible, meaningful, and cost-effective adjunct to biomedical treatment – addressing psychosocial and existential patient needs that often remain unmet. By triangulating multiple stakeholder perspectives, the study aims will identify practical considerations for integration into routine hematology practice, including optimal timing, training requirements, and potential barriers. It also offers longitudinal, multi-perspective insights into nurse-led narrative interviews at the early phase of hematologic diagnosis, an area scarcely investigated in prior literature. Ultimately, this work aims to strengthen person-centered hematologic care by honoring patient narratives and highlighting the therapeutic value of attentive listening, situating findings within both Italian and international research contexts, and advocating for narrative practice as a transformative approach capable of fostering trust, resilience, and humanized care.

Limitations

While the study seeks to deliver an in-depth understanding of nurse-led Narrative Intervention, several limitations warrant acknowledgment. The inherently small sample size characteristic of qualitative case studies may constrain transferability. Reliance on self-reported accounts and subjective reflections introduces potential bias, including social desirability and recall biases. The dual role of the

interviewing nurse as reflective writer may pose interpretative bias; however, this risk will be mitigated through methodological triangulation, reflexive thematic analysis, and peer debriefing, ensuring rigor and depth in interpretation. The recruitment strategy, based on purposive sampling within a single hospital unit, may limit representativeness and restrict diversity of experiences. Finally, as the research is confined to a single hematology unit, organizational and cultural factors may influence results in ways not generalizable to other settings.

This protocol therefore provides a methodological foundation for future studies and practical implementation, guiding the integration of narrative approaches in broader hematology practice.

Conclusion

This protocol describes a holistic qualitative single-case study designed to deepen understanding of nurse-led Narrative Intervention in patients newly diagnosed with hematologic malignancies. By capturing the voices of patients, caregivers, and healthcare professionals, it offers novel insights into relational and emotional dimensions of narrative practice. Unlike previous work, this study explicitly triangulates multiple perspectives and focuses on meaning-making shortly after diagnosis, addressing an underexplored gap in hematology care.

Despite inherent limitations, the protocol provides a methodological basis for future multicenter, longitudinal, or comparative studies aimed at embedding narrative approaches in routine care. Future developments may include the creation of evaluation tools and nurse training programs in narrative practice, fostering systematic integration of narrative approaches into clinical pathways. By emphasizing person-centered and relationally informed care, this study supports enhanced understanding and communication among patients, caregivers, and clinicians.

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Eye Care Practice in Intensive Care Units: A Rapid Review

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Abstract

Introduction. Ocular Surface Diseases (OSDs) are frequent yet often under-recognised complications in sedated and mechanically ventilated Intensive Care Unit (ICU) patients, in whom impaired eyelid closure and reduced tear film protection promote their development during critical illness. Although these conditions can significantly affect visual function and post-discharge quality of life, ocular care receives inconsistent attention in routine clinical practice. This rapid review aimed to identify and synthesise evidence-based nursing practices for the prevention and management of OSDs in the ICU within this patient population.

Methods. A rapid review was conducted between February and August 2024 and registered in PROSPERO (CRD42024540825). Searches were carried out in MEDLINE, CINAHL, Embase, and Google Scholar for full-text studies published in English between 2014 and 2024 that involved adult ICU patients receiving nurse-delivered ocular interventions. Methodological quality was appraised using the Joanna Briggs Institute critical appraisal tools. Given the heterogeneity of study designs and outcomes, a narrative synthesis was undertaken.

Results. Fourteen studies (n = 1,322 patients) from six countries met the inclusion criteria; most were randomised controlled trials (64%), and 72% were rated as having high methodological quality. Interventions included the application of preservative-free lubricants, vitamin A-based ointments, moisture chambers, polyethylene covers, eyelid taping, and structured nurse-led protocols. Moisture chambers and ointments demonstrated the strongest protective effects against exposure keratopathy, while the implementation of protocols and targeted nurse education significantly reduced ocular morbidity.

Discussion. The findings reaffirm the central role of ICU nurses in preventing OSDs through timely, evidence-based interventions. Standardising eye care practices may substantially reduce complications and enhance long-term

visual outcomes. Further high-quality multicentre studies are required to refine recommendations and support broader clinical implementation.

Keywords: Eye Care, Intensive Care Unit, Nursing Practice, Ocular Surface Diseases, OSD, Rapid Review

Introduction

In healthy individuals, the tear film functions as both a mechanical and biological barrier, maintaining ocular surface hydration and providing antimicrobial protection, while the eyelids act as a physical shield that prevents trauma and dryness (Hernandez & Mannis, 1997; Sorce et al., 2011). In hospitalised patients, particularly those admitted to Intensive Care Units (ICUs), these natural defence mechanisms are often impaired, increasing the risk of ocular surface damage and the development of Ocular Surface Diseases (OSDs) (Mobarez et al., 2022).

Several predisposing factors contribute to this vulnerability. Iatrogenic factors include mechanical ventilation (Kuruvilla et al., 2015), sedation (Imanaka et al., 1997; Mercieca et al., 1999) and neuromuscular blockade (Frazee et al., 2015), while patient-related factors comprise reduced consciousness (Mercieca et al., 1999) decreased tear secretion (Masoudi et al., 2014; Ousler et al., 2008; Saritas et al., 2013), reduced blink rate (Masoudi et al., 2014; Werli-Alvarenga et al., 2011), corneal reflex impairment (Rosenberg & Eisen, 2008; Saritas et al., 2013), incomplete eyelid closure (Jammal et al., 2012; Kuruvilla et al., 2015), and increased vascular permeability (Rosenberg & Eisen, 2008). Patients under deep sedation or pharmacological paralysis represent the most vulnerable group, as their ocular protection mechanisms are severely compromised, predisposing them to OSDs.

The most common ocular complications among ICU patients include dry eye, keratitis, conjunctivitis, and corneal abrasions, often secondary to infection, inflammation, or mechanical trauma (Mobarez et al., 2022). Among these, exposure keratopathy (EK) is the most frequent and clinically significant manifestation (Kuruvilla et al., 2015), affecting between 20-42% of ICU patients and up to 60% of those sedated for more than 48 hours (Grixti et al., 2013; Werli-Alvarenga et al., 2011). In patients undergoing

prolonged mechanical ventilation, corneal lesions have been reported in up to 59% of cases (Werli-Alvarenga et al., 2011), underscoring the need for effective preventive measures. If unrecognised or inadequately treated, EK may progress to ulceration, microbial keratitis, or permanent vision loss (Kuruvilla et al., 2015), significantly impacting post-ICU visual outcomes and quality of life.

Eye care therefore represents an essential component of nursing practice in ICU. However, the clinical complexity of critically ill patients and the prioritisation of life-sustaining treatments often result in inconsistent or insufficient ocular care, as clinical attention is primarily directed towards vital organ support (McHugh et al., 2008; Werli-Alvarenga et al., 2011). Despite the clinical relevance of this issue, comparative evidence on the effectiveness of preventive and therapeutic interventions remains limited, hindering the establishment of evidence-based best practices for ICU eye care (Alansari et al., 2015; Werli-Alvarenga et al., 2011). Consequently, interventions are frequently applied based on individual experience rather than standardised, evidence-informed protocols.

The aim of this rapid review is to identify, synthesise, and critically appraise the available evidence on nursing-led eye care practices for the prevention and management of OSDs in sedated, mechanically ventilated adult patients admitted to ICUs.

Methods

Study Design

A rapid review was conducted between February and August 2024, following the methodology recommended by the World Health Organization (WHO) and further refined by Langlois et al. into seven phases: (1) needs assessment and topic selection; (2) study development; (3) literature search; (4) study screening and selection; (5) data extraction; (6)

risk of bias assessment;

(7) knowledge synthesis (Langlois et al., 2019; Tricco et al., 2017).

In line with the aim of this review, the guiding research question was: “What are the best evidence-based practices for eye care in patients under sedation and invasive mechanical ventilation to prevent and treat Ocular Surface Diseases (OSDs) in Intensive Care Units (ICUs)?”

The review protocol was prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO) registration no. CRD42024540825 and subsequently published as a preprint on Preprints.org. (Cellura et al., 2025).

Search Strategy

The search strategy was developed collaboratively by all members of the research team and subsequently submitted for academic peer review (AMG). In February 2024, an initial exploratory search was conducted in Google Scholar and the MEDLINE database via PubMed, enabling the authors to identify relevant keywords and indexing terms for the final search strategy. From March to May 2024, comprehensive searches were carried out in MEDLINE (via PubMed), CINAHL (EBSCO), and Embase (Elsevier) using the search strings presented in Table 1.

Table 1. Search Strategy.

Last updated on 30 May 2024		
MEDLINE (PubMed)	• (((("dry eye syndromes"[MeSH Terms] OR "dry eye"[Text Word] OR "Keratoconjunctivitis"[Text Word] OR "keratoconjunctivitis infectious"[Text Word] OR "keratoconjunctivitis sicca"[Text Word] OR "ocular surface disease"[Text Word]) AND "eye care"[Text Word]) OR ("nursing"[MeSH Terms] OR "nursing"[All Fields] OR "nursings"[All Fields] OR "nursing"[MeSH Subheading] OR "nursing s"[All Fields]) AND "eye care"[Text Word])) AND "intensive care units"[Text Word]	n = 40
	• (((("dry eye syndromes"[MeSH Terms] OR "dry eye"[Text Word] OR "Keratoconjunctivitis"[Text Word] OR "keratoconjunctivitis infectious"[Text Word] OR "keratoconjunctivitis sicca"[Text Word] OR "ocular surface disease"[Text Word]) AND "eye cleaning"[Text Word] OR "artificial tear drops"[Text Word] OR "lubricating gel"[Text Word] OR ("Over"[All Fields] AND "eye application"[Text Word]) OR "vitamin a eye ointment"[Text Word]	n = 108
CINAHL (EBSCO)	• (((Ocular surface disease) OR (exposure keratitis) OR (keratoconjunctivitis, infections) AND (eye Care) OR (artificial tear drops) OR (lubricating gel) OR (vitamin A eye ointment) AND (intensive care units))	n = 910
EMBASE (Elsevier)	• ('ocular surface disease'/exp OR 'dry eye'/exp OR 'exposure keratitis'/exp OR 'keratoconjunctivitis'/exp) AND ('eye care'/exp OR 'nursing care'/exp)	n = 247

Legend: This table presents the complete search strategy used to identify relevant studies included in the review. Each row corresponds to one of the databases searched MEDLINE (via PubMed), CINAHL (via EBSCO), and EMBASE (via Elsevier). For each database, the exact search string is reported, detailing the keywords, Boolean operators (AND, OR), and the controlled vocabulary or subject headings specific to that source. The search was last updated on 30 May 2024, and the total number of records retrieved from each database is shown in the column on the right.

Study Selection

In accordance with methodological standards for systematic reviews (Page et al., 2020), a three-phase process of screening, eligibility assessment, and inclusion was conducted by two independent ICU experts (LC and SGS). A third independent ICU reviewer (SL) was consulted to resolve any discrepancies or disagreements arising during the process. The Rayyan software (free version, v.1.4.3) for systematic reviews (Ouzzani et al., 2016) was used to manage the screening and selection workflow. The following inclusion criteria were applied during the search phase: (1) adults (≥ 18 years) admitted to ICUs who were

sedated and mechanically ventilated; (2) primary studies available in full text and published in English; (3) studies published within the past 10 years addressing the nursing contribution to eye care. The exclusion criteria were: (1) studies involving paediatric populations (<18 years); (2) settings other than intensive care (e.g. recovery rooms or operating theatres); (3) articles not primarily focused on nursing-led eye care.

Quality Methodological Assessment of Included Studies

The methodological quality of the included studies was critically appraised using the

Joanna Briggs Institute (JBI) Critical Appraisal Checklists (Aromataris et al., 2015), each selected according to the respective study design (experimental or observational). The tools were applied independently by two reviewers (LC and MC) to assess the risk of bias across key methodological domains, including participant selection, management of confounding factors, outcome measurement, and statistical analysis. Each checklist comprised 8 to 13 items, rated as Yes (Y), No (N), Unclear (UC), or Not applicable (NA). The appraisals were expressed qualitatively at the domain level, in accordance with JBI methodological guidance.

Any discrepancies between reviewers were resolved through discussion and consensus. The inter-rater agreement between the two independent reviewers (LC and MC) was estimated using Cohen's kappa coefficient (κ), which indicated a substantial level of concordance.

Data Extraction

Two independent reviewers (LC and SGS) individually reviewed the full text articles and extracted the relevant data. Any disagreements between reviewers were resolved through discussion and consensus. All data extracted from each included study were entered into a Microsoft Excel 2016 spreadsheet (Mac version 15.26) and organised according to the following variables: (1) first author and year of publication; (2) country; (3) study design; (4) participant characteristics; (5) interventions; (6) main outcomes.

Data Analysis and Synthesis

Due to the clinical and methodological heterogeneity of the included studies — in terms of intervention strategies, duration, and study design — it was not feasible to perform a meta-analysis of the extracted data. Therefore, the results were summarised narratively. The target variables were first categorised according to the type and extent of ocular damage and subsequently organised chronologically within the data extraction table. Additional findings concerning the general characteristics and methodological quality (risk of bias) of the included studies were presented in customised summary tables.

Results

Search Results

A total of 1305 records were initially identified through database searches. Following the application of automated screening tools and the removal of duplicates, 1095 records were excluded. The remaining 210 records underwent title and abstract screening. Of these, 167 studies were excluded for not meeting the predefined inclusion criteria. Subsequently, 43 full text articles were retrieved for detailed evaluation, of which 12 studies met the inclusion criteria and were included in the review. An additional two eligible studies were identified through manual searches, including Google Scholar and backward citation tracking. In total, 14 studies were included in the final synthesis. The study selection process is illustrated in Figure 1.

Studies Attributes

Details of the characteristics of the included studies are reported in Table 2 (page 106). All articles were published within the past ten years, representing research conducted across six countries. Data synthesis revealed that 43% ($n = 6$) of the studies were published before 2019, while 57% ($n = 8$) were published between 2020 and 2024. The majority of the studies 79%, ($n = 11$) were conducted in Asia. Regarding study design, 64% ($n = 9$) were experimental, with a predominance of Randomised Controlled Trials (RCTs), whereas 36% ($n = 5$) were observational. Across the included studies, ICU patients were sedated, mechanically ventilated, and at risk of OSDs, with sample sizes ranging from 27 to 371 participants. A range of interventions was investigated, including polyethylene covers, preservative-free artificial tears, vitamin A and antibiotic ophthalmic ointments, moisture chambers, eyelid taping techniques, and structured nurse-led eye care protocols. Comparative effectiveness varied among interventions; however, polyethylene covers and ophthalmic ointments consistently emerged as effective strategies for preventing EK and other ocular complications. A smaller subset of studies also examined the impact of nursing education and protocol adherence on patient outcomes, demonstrating significant reductions in ocular morbidity following structured nurse training. Overall, the included studies provided clinically meaningful yet methodologically heterogeneous

evidence, supporting the development of evidence-based nursing protocols for ocular surface management in the intensive care setting.

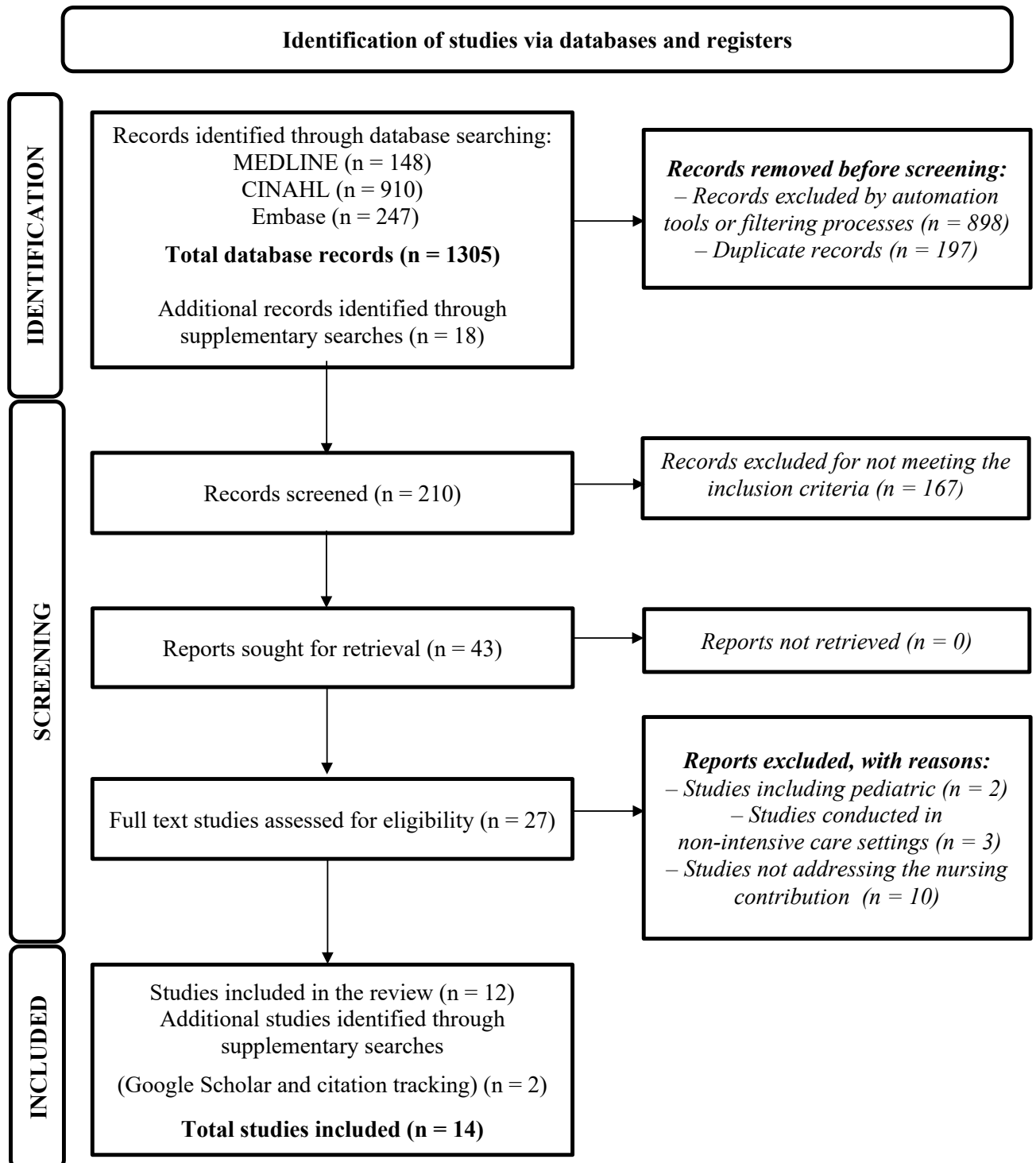


Figure 1. Preferred Reporting Items for Systematic Review and Meta-Analyses PRISMA flow diagram.

Legend: Illustrating the identification, screening, eligibility, and inclusion phases of the rapid review. The process summarises the systematic selection of studies retrieved from electronic databases and supplementary sources according to predefined inclusion and exclusion criteria, resulting in the final sample analysed.

Methodological Quality

As shown in Table 4, analysis of the data using the JBI Critical Appraisal Checklists revealed that 72% (n = 10) of the studies were of high methodological quality, 28% (n = 4) were of moderate quality, and none were classified as low quality. Among the observational studies, the data indicated overall good quality in terms of study design and data collection, though some limitations were noted regarding sample representativeness and the control of selection bias. Conversely, the experimental studies generally met the criteria for randomisation and blinding, although several studies reported follow-up limitations that could affect the reliability and internal validity of their findings. Agreement between the two independent reviewers was substantial ($\kappa = 0.66$), indicating good inter-rater reliability in the methodological quality assessments.

Table 3. Studies Attributes.

Attributes	n.	%
Year of publication		
from 2014 to 2019	6	(43%)
from 2020 to 2024	8	(57%)
Continent		
United States of America & Canada	0	(0%)
Asian & Middle East	11	(79%)
United Kingdom & Europe	2	(14%)
Australia	0	(0%)
Latin America	1	(7%)
Study design		
Observational	5	(36%)
Experimental and quasi-experimental	9	(64%)

Legend: Descriptive characteristics of the included studies, grouped by year of publication, continent, and study design. Abbreviations: n, number of studies, and %, percentage of total

Table 4. Quality Assessment of the Included Studies.

Prospective/Randomised Controlled/Cross-Over Clinical Trials	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Overall	
<i>Kalhari, 2015</i>	+	-	+	+	-	-	-	+	+	+	+	+	+	Good methodological quality, with moderate limitations due to lack of blinding.	
<i>Bendavid, 2017</i>	+	+	+	+	-	+	+	+	+	+	+	+	+	High methodological quality, low risk of bias.	
<i>Babamohamadi, 2018</i>	-	-	+	-	-	-	-	+	+	+	+	+	+	Moderate methodological quality, with potential reporting bias.	
<i>De Araujo, 2019</i>	+	+	+	+	+	+	+	+	+	+	+	+	+	High methodological quality, negligible risk of bias.	
<i>Badparva, 2021</i>	+	+	+	+	+	+	+	+	+	+	+	+	+	High methodological quality, negligible risk of bias.	
<i>Nikseresht, 2021</i>	+	?	+	+	?	?	+	+	+	+	+	+	+	Good methodological quality, minor uncertainties in some domains.	
<i>Pourghaffari, 2021</i>	+	?	+	?	-	?	+	?	-	+	+	+	?	Moderate methodological quality, with some risk of bias.	
<i>Mobarez, 2022</i>	+	+	+	+	+	-	+	+	+	?	+	+	+	Good methodological quality, low risk of bias.	
<i>Rezaei, 2022</i>	+	+	+	+	+	?	-	+	+	+	+	+	?	Good methodological quality, minimal bias.	
Case Report Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8							
<i>Yu, 2021</i>	+	+	+	+	+	+	-	+							Good methodological quality, within the inherent limits of the design.
Cohort Studies	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11				
<i>Kousha, 2018</i>	+	+	+	+	+	+	+	+	+	/	+				High methodological quality, low risk of bias.
<i>Pai, 2023</i>	+	+	+	+	-	-	+	+	+	/	+				Moderate methodological quality, with potential bias related to confounders.
Cross Sectional Studies	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8							
<i>Dhanapala, 2021</i>	+	+	+	?	-	+	+	-							Moderate methodological quality, with potential analytical bias.
<i>Vyas, 2018</i>	+	+	+	+	-	+	+	+							Good methodological quality, with potential analytical bias.

Legend: Quality appraisal of included studies using JBI Critical Appraisal Checklists, applied according to study design. “+” = criterion met; “-” = not met; “?” = unclear; “/” = not applicable. Overall quality classified as high, good, or moderate.

Table 2. Data Summary.

First author, year	Country	Study design	Intervention	
Kalhari, 2015	Iran	Randomised Clinical Trial	Liposic® ointment applied to the eyelid margin every 5 hours, ensuring complete coverage of the cornea before manually closing the eyelid vs transparent polyethylene cover over the eyes extending from the eyebrow to the cheekbone, replaced every 12 hours vs application of preservative free artificial tears, two drops in each eye every 2 hours.	
Bendavid, 2017	Israel	Prospective Randomised Pilot Study	Ocular lubricants vs bandage contact lenses vs punctal plugs for the prevention and management of OSDs	
Babamohamadi, 2018	Iran	Randomised Clinical Trial	Each patient received vita-min A ointment in one eye every 6 hours for 5 days vs the contralateral eye was treated with a polyethylene film Mois-ture Chamber replaced every 12 hours.	
Kousha, 2018	United Kingdom	Two phase Prospective Cohort Study	Introduction of a nurse-led eye care protocol: Ocular cleansing with sterile gauze and isotonic physiological solution, application of Lacri-Lube® every 6 hours and Application of Lacri-Lube® before sleep.	
Vyas, 2018	India	Cross Sectional Study	Evaluation of nursing adherence to an evidence-based eye care protocol and its implications for patient-level ocular protection.	
de Araujo, 2019	Brazil	Randomised Clinical Trial	Lacribell® artificial tears vs Vidisic® artificial tear gel for the prevention of OSDs in critically ill patients	
Badparva, 2021	Iran	Randomised Clinical Trial	Assessment of adherence to standardized eye care practices, including: • Microporous tape eyelid closure; • Lubricant ointment application; • Combined use of ointment and tape.	
Dhanapala, 2021	United Kingdom	Cross-Sectional Study	Assessment of adherence to standardized eye care practices, including: • Microporous tape eyelid closure; • Lubricant ointment application; • Combined use of ointment and tape.	
Nikseresht, 2021	Iran	Prospective Clinical Trial	Three different ophthalmic treatments were applied for five consecutive days (one per group) vs standard nursing care (contralateral eye as control): • Polyethylene cover applied once a day and replaced as needed; • Polyethylene cover applied once daily, supplemented with artificial tears every 8 hours; • Polyethylene cover applied once daily, supplemented with Lubratex® ointment every 8 hours.	
Pourghaffari, 2021	Iran	Cross-Over Clinical Trial	Implementation of a structured eye care protocol following specific nursing training vs no treatment in the control eye.	
Yu, 2021	China	Case Report	Both eyes were cleansed daily with sterile water. The right eye received a 2 cm strip of carbomer gel every 6 hours, later replaced with ofloxacin ophthalmic ointment applied every 6 hours. Subsequently, a moisture chamber was applied as an adjunctive measure.	
Mobarez, 2022	Iran	Randomised Clinical Trial	An eye care protocol based on eyelid position was implemented as follows: • Group 1: one drop of hypromellose 0.3% instilled into both eyes every 2 hours, continued for 4 hours; • Group 2: three drops of hypromellose 0.3% every 2 hours for 6 hours, with horizontal eyelid taping to maintain closure; • Group 3: three drops of hypromellose 0.3% every 2 hours for 8 hours, with horizontal eyelid taping applied.	
Rezaei, 2022	Iran	Randomised Clinical Trial	Nurses applied artificial tears (2 drops) plus a simple ophthalmic ointment every 4 hours, followed by eyelid taping to ensure full closure, for patients with lagophthalmos, passive blinking exercise were added every 30 minutes over one week vs nurses performed hand hygiene and administered artificial tears (2 drops) every 4 hours (control).	
Pai, 2023	India	Prospective Cohort Study	Implementation of an eye care protocol following structured nurse training on ocular assessment and prevention of OSDs.	

Legend: ICU: Intensive Care Unit; **vs:** versus; **EK:** Exposure Keratopathy; **OSD:** Ocular Surface Disease; **RR:** Relative Risk; **OR:** Odds Ratio; χ^2 : Chi

	Participant profile	Main outcome
	- n = 96 ICU patients; - n = 32 Liposic® carbomer 980 ointment group; - n = 32 polyethylene film cover group; - n = 32 artificial tear drops group. Homogenous groups.	Analysis revealed that the polyethylene film cover demonstrated the greatest preventive efficacy, with a mean keratopathy score of 0.59 ± 0.66 significantly outperforming the other interventions ($p = 0.001$). Although no statistically significant difference was observed between the Liposic® carbomer 980 ointment and artificial tear drops ($p = 0.84$), the ointment group showed a lower frequency and severity of corneal abrasions (mean = 1.13 ± 0.75 , $p < 0.001$), indicating a superior protective effect on the corneal surface.
	- n = 104 ICU patients; - n = 38 ocular lubricants group; - n = 33 bandage contact lenses group; - n = 33 punctal plugs group. Homogenous groups.	The severity of EK increased significantly in the ocular lubricant group ($p = 0.01$) for both eyes, whereas no worsening was observed in either the bandage contact lens and punctal plug groups. In a post hoc analysis of patients with initially abnormal ophthalmic findings, significant keratopathy healing occurred in the bandage contact lens group ($p = 0.02$ and $p = 0.018$ for the left and right eyes, respectively*) and in the right eye of the punctal plug group ($p = 0.005$). No improvement was observed in the eyes of the group treated with eye lubricant.
	- n = 38 comatose patients in intensive care (n = 64 eyes); - n = 38 eye vitamin A ointment (VAEO) group. - n = 38 eye Moisture Chamber (MC) group. Homogenous groups.	Schirmer's test value increased by 2.06 mm in the VAEO group ($p < 0.001$) and slightly decreased by 0.15 mm in the MC group ($p = 0.66$). Vitamin A ointment has been shown to be more effective than humidification chambers in preventing OSDs in the eyes of patients admitted to ICU and is therefore recommended as the preferred preventive strategy.
	- n = 371 ICU patients sedated and mechanically ventilated, and non-sedated mechanically ventilated; - n = 257 phase 1 group (observational phase); - n = 114 phase 2 group (post-protocol implementation).	During phase 1, the overall incidence of EK was 21%, rising to 56% among mechanically ventilated patients [χ^2 (1, n = 257) = 80.8; $p < 0.001$]. During phase 2, the overall EK incidence significantly decreased to 2.6% (3 cases) [χ^2 (1, n = 371) = 18.6; $p < 0.001$]; demonstrating the effectiveness of systematic nursing interventions in preventing OSDs.
	n = 120 nurses from six multispecialty hospitals caring for mechanically ventilated ICU patients.	Only 5% received systematic, protocol-based ocular protection. Approximately 43% of patients had their eyelid closure regularly assessed, while 48% received routine ocular cleansing with sterile saline. Patients cared for by nurses aware of EK were significantly more likely to receive adequate ocular protection.
	- n = 140 ICU patients; - n = 70 Lacribell® artificial tears group; - n = 70 Vidisic® artificial tear gel group. Homogenous groups.	The use of Vidisic® artificial tear gel was significantly more effective in preventing dry eye than Lacribell® liquid artificial tears, with a RR = 0.40: 95% CI, 0.16-0.96 ($p = 0.04$). These findings indicate that gel based lubricants provide superior and longer lasting ocular protection for ICU patients at risk of OSDs.
	- n = 41 ICU patients (64 eyes); - n = 41 eye Lubratex® ointment group; - n = 41 eye Vitamin A ointment group. Homogenous groups.	A post-intervention conducted after one month (n = 24) demonstrated that 67% of patients received eye lubrication, and 50% had eyelids taped in accordance with ICU eye care guidelines for the supine position. Among patients treated in the prone position, 100% received both ocular lubrication and microporous taping, reflecting full compliance with best-practice recommendations. These findings suggest improved protocol adherence in prone patients but persistent variability in eye care practices among supine ICU patients.
	n = 27 mechanically ventilated ICU patients.	A post-intervention conducted after one month (n = 24) demonstrated that 67% of patients received eye lubrication, and 50% had eyelids taped in accordance with ICU eye care guidelines for the supine position. Among patients treated in the prone position, 100% received both ocular lubrication and microporous taping, reflecting full compliance with best-practice recommendations. These findings suggest improved protocol adherence in prone patients but persistent variability in eye care practices among supine ICU patients.
	- n = 156 ICU patients (n = 312 eyes); - n = 52 eye polyethylene cover group (1); - n = 52 eye polyethylene cover and artificial tear drops group (2); - n = 52 eye polyethylene cover and Lubratex® ointment group (3). No significant differences in demographic characteristics and confounding variables.	No statistically significant difference in the severity of lagophthalmos was found between the three groups ($p = 0.93$). However, the eyes of patients in the group treated with polyethylene cover and artificial tears showed less severe lagophthalmos than those in the other two groups, suggesting a modest additive effect of the combination of lubrication and occlusive protection in maintaining eyelid closure.
	- n = 32 ICU patients (64 eyes); - n = 32 eye intervention group; - n = 32 eye control group.	No significant differences in dacryorrhea or hyperaemia were observed between groups from days 2 to 7 ($p < 0.05$). However, the incidence of xerophthalmia was significantly lower in the treated eyes from days 4 to 7 ($p = 0.0001$), accompanied by a parallel reduction in corneal opacity observed from day 4 onward in the intervention group ($p = 0.0001$).
	n = 1 female patient with right-sided lagophthalmos following brain injury.	Neither lubricating gel, antibiotic ointment, nor bandage lenses proved effective in preventing or resolving EK. Application of a moisture chamber, however, successfully controlled corneal ulceration, avoiding the need for tarsorrhaphy and restoring corneal protection.
	- n = 65 ICU patients; - n = 34 intervention group (stratified into three subgroups according to eyelid position); - n = 31 control group. No significant differences were observed in demographic characteristics or confounding variables.	Implementation of the eye care protocol significantly reduced the incidence of OSDs compared to standard care EK: OR = 3.1 ($p = 0.02$); conjunctivitis: OR = 3.7 ($p = 0.01$); dry eye: OR = 5.3 ($p = 0.001$); corneal ulcer: OR = 4.8 ($p = 0.003$). These findings demonstrate that a structured, position based nurse-led eye care protocol effectively reduces the occurrence of OSDs among ICU patients.
	- n = 51 ICU patients (102 eyes); - n = 51 eye intervention group; - n = 51 eye control group. Homogenous groups.	The prevalence and incidence of EK were significantly lower in the intervention group ($p = 0.003$). A significant difference was also found in the prevalence of EK in the eyes of patients with lagophthalmos ($p = 0.03$). These results indicate that the combined use of artificial tears, ophthalmic ointment, eyelid bandaging and periodic blinking exercises effectively reduces both the prevalence and severity of EK.
	- n = 200 Medical ICU patients; - n = 100 before training group; - n = 100 after training. Homogenous groups.	The incidence of ocular morbidity decreased significantly after training from 63% to 25% ($p < 0.001$). Patients with lagophthalmos and a length of ICU stay >7 days demonstrated a higher risk of developing.

Squared Test; **CI**: Confidence Interval; **p**: p-value.

Discussion

This rapid review included 14 international full text studies, comprising RCTs, cohort studies, cross-sectional studies, and one case report, encompassing a total of approximately 1,322 sedated and mechanically ventilated adult patients admitted to ICUs. The methodological quality, assessed using the JBI Critical Appraisal Tools, was overall high, with 72% of studies rated as high quality and 28% as moderate, while none were classified as low quality. Most studies demonstrated robust design, transparent reporting, and appropriate analytical approaches. Despite heterogeneity in sample sizes, assessment instruments, and intervention types, the findings consistently reinforce the central role of nurses in preserving ocular surface integrity through timely, evidence-based care.

The narrative synthesis highlighted that the primary objective of ocular care in this patient population is the maintenance of ocular surface integrity through adequate cleansing and hydration, primarily by minimising tear film evaporation. Interventions were commonly tailored to the degree of lagophthalmos (Hearne et al., 2018; Kousha et al., 2018; Mobarez et al., 2022). Across all studies, early diagnosis and prevention of lagophthalmos emerged as the first step in preventing ocular surface damage (Rosenberg & Eisen, 2008; Vyas et al., 2018). Regular nursing assessments of eyelid closure, supported by systematic documentation, were essential for early detection of ocular exposure and for initiating protective interventions promptly.

Ocular cleansing was one of the most frequently reported preventive measures, recommended every 2-4 hours or at least once per nursing shift, using sterile gauze moistened with isotonic saline or sterile water (Aromataris et al., 2015; Hearne et al., 2018; Kousha et al., 2018; Vyas et al., 2018; Werli-Alvarenga et al., 2011). Direct irrigation, however, is not recommended due to the risk of contamination and increased ocular surface irritation (Babamohamadi et al., 2018; Werli-Alvarenga et al., 2011). Lubrication using preservative-free artificial tears or ophthalmic ointments was effective in maintaining corneal hydration by reducing evaporation and friction (Hearne et al., 2018; Kousha et al., 2018; Vyas et al., 2018). Vitamin A-based ointments offered

additional epithelial protection and prolonged surface retention (Babamohamadi et al., 2018; Badparva et al., 2021), particularly in patients with persistent lagophthalmos.

Moisture chambers and polyethylene film covers were identified as effective mechanical barriers, reducing tear evaporation and creating a micro-humid environment (Babamohamadi et al., 2018; Kalhori et al., 2015; Nikseresht et al., 2021). Their use was especially beneficial in patients under deep sedation or neuromuscular blockade, where blinking and eyelid closure are impaired (Dhanapala & Sabaretnam, 2021; Rosenberg & Eisen, 2008). In selected cases, antibiotic ointments were used prophylactically or therapeutically to prevent ocular infection (Yu et al., 2021). Eyelid taping with microporous adhesive tape, when correctly applied, ensured complete eyelid closure and protection from environmental irritants (Dhanapala & Sabaretnam, 2021; Mobarez et al., 2022).

Only one study included patients in the prone position, limiting generalizability (Dhanapala & Sabaretnam, 2021). However, Sanghi et al. and Lightman & Montgomery recommended similar eye care strategies for prone and supine patients, including lubrication, eyelid taping, and postural adjustments such as anti-Trendelenburg positioning and head rotation every four hours (Lightman & Montgomery, 2020; Sanghi et al., 2021). Some studies also examined environmental factors influencing ocular health, such as humidity (50-60%), temperature (22.5-25.5 °C), and light exposure (Werli-Alvarenga et al., 2011). Optimising ambient humidity and avoiding continuous direct lighting were found to support ocular surface hydration and reduce irritation (Demirel et al., 2014; NSW, 2024). Although secondary to direct ocular interventions, these contextual measures complement nursing practices and should be integrated into routine care. Nevertheless, it should be clarified that these environmental recommendations derive mainly from expert consensus rather than direct evidence from the included studies; they therefore represent adjunctive best practices designed to support primary ocular care strategies.

The predominance of eye-focused interventions reflect the local pathophysiology of OSDs, typically resulting from lagophthalmos, reduced tear production, and tear film instability associated with sedation and mechanical ventilation (Hernandez & Mannis, 1997; Kuruvilla

et al., 2015; Mobarez et al., 2022). Such topical approaches are the most direct, measurable, and feasible within nursing practice. Nevertheless, ocular health is also influenced by systemic and organisational factors, including sedation management, ventilator settings, fluid balance, and environmental control, confirming the multidimensional and interdisciplinary nature of eye care in the ICU (Ahmadinejad et al., 2020). Effective prevention thus requires collaboration among nurses, physicians, and ophthalmologists, with nurses playing a pivotal role in early recognition, prevention, and documentation of ocular surface conditions.

Importantly, ICU nurses have demonstrated the ability to detect OSDs, such as EK and keratoconjunctivitis, with acceptable sensitivity and specificity (McHugh et al., 2008). Regular nursing assessments and documentation of ocular condition facilitate early detection and timely management, improving clinical outcomes and supporting continuity of visual health after discharge.

This rapid review therefore underscores an often-overlooked dimension of patient safety in ICU: the prevention and management of OSDs in deeply sedated, mechanically ventilated patients. Despite their impact on visual function and post-ICU quality of life, these complications remain frequently neglected in daily practice.

Implication for Practice

To address the persistent gaps in ocular surface care for critically ill patients, the findings of this review support the development of a nurse-led, evidence-based protocol, “Eye Care, You Care”, designed for integration into standard intensive care routines (Figure S1 from Supplementary Material).

Drawing on high-quality empirical evidence and expert consensus, the protocol translates best available research into a structured yet flexible framework applicable across diverse ICU settings. It provides clear, actionable guidance on essential nursing interventions, including eye cleansing frequency, lubrication regimens, and the use of moisture chambers to preserve corneal hydration, in accordance with current international recommendations (Lightman & Montgomery, 2020; NSW, 2024). Importantly, the protocol underscores the pivotal role of ICU nurses in the early identification and prevention of OSDs by embedding systematic ocular

assessment within routine patient monitoring (McHugh et al., 2008). By fostering timely intervention and interdisciplinary collaboration, this approach promotes a standardised and shared model of eye care, thereby enhancing patient safety, improving clinical outcomes, and supporting long-term visual recovery after critical illness.

Limits of the Study

Despite the methodological rigour of this rapid review, several limitations warrant consideration. First, the marked heterogeneity in study designs, intervention protocols, and outcome measures precluded any form of meta-analytic synthesis, preventing the derivation of quantitative effect estimates or comparative efficacy analyses. Moreover, several studies reported outcomes per eye rather than per patient, introducing the potential for intra-patient correlation, and limiting statistical independence. Second, the external validity of some studies was constrained by non-probabilistic sampling and single-centre designs, both of which may have introduced selection bias and restricted the generalisability of findings to broader ICU populations or resource-limited settings. Finally, only one study addressed patients managed in the prone position, thereby limiting the strength of evidence for this subgroup. Although expert consensus supports applying similar ocular care strategies as those used in supine patients, these recommendations remain extrapolations rather than empirically validate

Conclusion

This rapid review presents the first comprehensive synthesis of evidence concerning ocular care in critically ill, sedated, and mechanically ventilated patients admitted to ICUs. The findings reveal a consistent body of evidence supporting targeted, evidence-based nursing interventions – such as regular ocular cleansing, preservative-free lubrication, and the application of moisture chambers – tailored to the degree of lagophthalmos and environmental conditions.

These results underscore the urgent need to standardise and harmonise nursing eye care practices through structured, evidence-based protocols that can be seamlessly integrated into routine critical care. Implementing such

protocols has the potential to significantly enhance patient safety, preserve ocular surface integrity, and improve post-ICU visual outcomes. Despite heterogeneity in study designs and outcome measures, the overall methodological quality provides a robust foundation for clinical translation. The proposed nurse-led “Eye Care, You Care” protocol operationalises this evidence into a practical, adaptable framework for daily ICU nursing practice, promoting consistency, accountability, and high standards of care. Further multicentre research is warranted to validate these interventions — particularly in patients managed in the prone position and to support their broader adoption across diverse intensive care settings.

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Infective Risk Related to Peripherally Inserted Venous Access under Ultrasound Guidance by Trained Nurses: A Retrospective Observational Study

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Abstract

Introduction. Patients admitted to infectious diseases units frequently require prolonged intravenous therapy and repeated blood sampling, making reliable peripheral venous access essential. However, conventional peripheral cannulation is often challenging due to poor vein quality and repeated insertions. To enhance vascular access management, nurses were trained to insert peripheral venous access devices such as mini-midline and midline catheters. This study aimed to evaluate the infectious risk associated with these devices, with particular focus on catheter tip pathogen colonization.

Methods and materials. A retrospective observational study was conducted at an Infectious Diseases Clinic of a university hospital in Northeast Italy. Medical records of patients who received a mini-midline or midline catheter inserted by trained nursing staff between January and August 2023 were reviewed. Data were collected for 50 consecutive patients and included indications for catheter removal, occurrence of suspected infection, and results of catheter tip culture examinations when available. Descriptive analysis was performed to assess the incidence of suspected infection and confirmed device colonization.

Results. Among the 50 evaluated catheters, 6 (12.0%) were removed due to suspected infection. Catheter tip cultures were performed in these cases, and only one device showed microbiological growth. The single positive culture identified *Staphylococcus epidermidis* and was obtained from a mini-midline catheter inserted using the Seldinger technique; notably, this catheter had been removed for reasons unrelated to infection. No confirmed catheter-related infections were

documented.

Discussion. These findings suggest that mini-midline and midline catheters are associated with a low risk of infectious complications, particularly device colonization, when inserted by adequately trained nurses. This supports their safe use in patients requiring medium-term venous access in infectious diseases settings. Nevertheless, the retrospective design and limited sample size restrict the generalizability of the results. Larger, prospective studies are warranted to further confirm the safety profile of these devices.

Keywords: Mini-midline, Midline, Infective Risk, Ultrasound Guidance

Introduction

Patients admitted to the infectious diseases department often require intravenous antimicrobial therapy and frequent blood draws, both to monitor their overall clinical progress and to perform Therapeutic Drug Monitoring (TDM) of the antibiotics. For these reasons, the availability of a venous access from which it is also possible to perform blood sampling and which, at the same time, guarantees patient comfort, the lowest possible risk of infection, and the greatest temporal durability depending on the intravenous therapies for which it is used is empirically preferable. In terms of peripheral venous access, in addition to the commonly used Peripheral Intravenous Catheter (PIV), midline and mini-midline catheters also known as long peripheral cannulas (LPCs) have become increasingly widespread in recent years. The mini-midline devices represent an intermediate option between PIVs and midlines, with lengths ranging from 6 to 15 cm and a dwell time of up to 4 weeks. For comparison, PIVs in terms of length range from 4.8 cm to 6.35 cm, and the average postinsertion lifespan is approximately 60–96 h. While midlines range from 8 to 12 cm, and the average postinsertion lifespan is about 7 to 14 days. They are typically inserted in the arm under ultrasound guidance using the Seldinger technique (Quin et al., 2019). Some studies in the literature show that mini-midlines placed under ultrasound guidance have better performance compared to traditional PIV in various aspects, especially in patients with poor venous access (Badger, 2019; Qin et al., 2021). The use of ultrasound for implanting these devices also appears to have a preventive effect

against thrombophlebitis, extravasation, and site infection without bacteremia, and overall is associated with a lower risk of complications (Scoppettuolo et al., 2016).

As indicated by the Italian GAVeCeLT group (“Gli Accessi Venosi Centrali a Lungo Termine”), a mini-midline should be placed in any hospitalized patient (whether a DIVA patient, i.e. Difficult IntraVenous Access patient, or a non-DIVA patient) requiring intravenous drug administration with a treatment duration > 7 days or in DIVA patients even for treatments lasting < 48 hours (GAVeCeLT, 2024). For this reason, given the short duration of antimicrobial therapies performed in this clinic -which varies from one week, up to three to four weeks- in 2022, several nurses from the Infectious Diseases Clinic at Udine Hospital were trained in the placement of these devices. They subsequently implanted them in various patients, optimizing their care. In this study, we evaluated the safety of these devices by assessing the infectious risk related to their placement, as described, in terms of pathogenic colonization. Given the lower risk associated with peripheral access compared to central lines, the longer dwell time of mini-midlines, and the relative simplicity of their placement (whether using all-in-one devices or the Seldinger technique) as well as the increased patient comfort, our objective was to formally validate the use of this device for infusion therapy and to promote its wider adoption.

Methods and materials

This retrospective study was reported in accordance with the STROBE (Strengthening

the Reporting of Observational Studies in Epidemiology) checklist for observational studies (von et al., 2014).

Data collection occurred by consulting the medical records of patients admitted to the Infectious Diseases Clinic at Udine Hospital from January to August 2023. The admission regimen could be either regular (ordinary) or day hospital. The inclusion criteria consisted of patients who: 1) were aged ≥ 18 years, 2) were admitted to the study centre, and 3) required placement of one of the devices under study. Out of the 91 eligible patients, 50 were included in the study (Figure 1).

The implanted devices were of three different types: "All in One" mini-midline (PowerGlide Pro™ Midline Catheter 18G – 10cm, SKU/REF F218108PT – BD), mini-midlines placed using the Seldinger technique (Leader-Cath® artero-venous in PE 18G - 10cm, REF 115.11 – Vygon), and midlines (PowerMidline™ Catheter 4Fr/18G - 20cm single-lumen, REF P6154118 – Bard). A higher proportion of patients receiving "All in One" devices were treated for multiple medications or frequent blood draws (58.3%) compared to those receiving other devices for poor venous access (57.9%). To assess the infectious risk, it was decided to include in the analyses only those devices for which the tip was sent for culture examination.

The data were collected by completing a checklist on the EUSurvey platform. This is a free, online survey management platform developed by the European Commission's DG DIGIT under the ISA²/Digital Europe programmes. The checklist gathered data from three distinct phases of the process: device placement (patient-related characteristics such as age, gender, originating department, reason for admission, medical history, and details about the implanted device), removal of the device (including data and reasons for removal), and the outcome of the culture examination. The data collected in this study concern exclusively devices whose tip was subjected to post-removal culture in the laboratory. The catheter tip culture analysis involves incubating the catheter tip in a sterile environment to detect and identify microbial growth, helping to diagnose potential infections. This allowed the verification of potential colonization by pathogen of the device, indicating the mere presence of microorganisms inside the catheter (Pittiruti et al., 2017). To confirm the presence of an infection, a diagnosis of Catheter-Related Bloodstream Infection (CRBSI)

must be made, i.e. a blood test which shows that the catheter itself is conclusively the cause of the bloodstream infection. The diagnosis of catheter-related bloodstream infection (CRBSI) requires both clinical symptoms and laboratory evidence. (Centers et al., 2024; Pittiruti et al., 2017), typically based on the Differential Time to Positivity (DTP) method. This involves obtaining blood cultures from both the suspected venous access device and a peripheral vein, allowing the laboratory to assess the time difference in culture positivity.

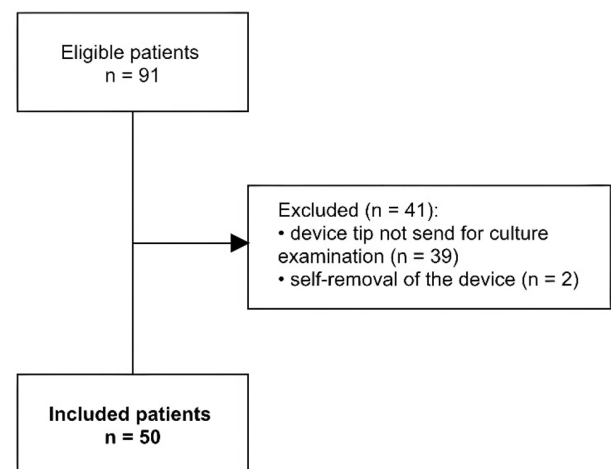


Figure 1. Patient selection flow-chart.

Statistical Analysis

We tested the normal distribution of continuous variables using the Shapiro-Wilk test. This is a statistical test for normality. It assesses whether a dataset comes from a normally distributed population by calculating a W statistic based on the correlation between the ordered sample values and the expected values from a normal distribution. Low W values indicate deviations from normality (Shapiro et al., 1965). As the sample size was < 5000 , normally distributed variables were presented with the mean and standard deviation ($\pm$ SD), while non-normally distributed ones were represented with the median and interquartile range (IQR).

For categorical and dichotomous variables, absolute frequency (n) and relative percentage (%) were reported. Categorical variables represent distinct groups (e.g., blood type, profession), while dichotomous variables have only two possible values (e.g., yes/no, male/female) (Shapiro et al., 1965).

Results were classified depending on the setting

(clean or sterile environment) and also depending on the type of device and technique (all-in-one, Seldinger adapted for mini-midlines, Seldinger for midlines). Statistical significance was defined as $p < 0.05$. Statistical analyses were performed using the software "R" version 4.2.2 "Innocent and Trusting" (The R Foundation for Statistical Computing - 31/10/2022) with the assistance of the "R Commander" package (Rcmdr) version 2.8-0. Categorical variables were compared using the Chi-square test when appropriate.

The aim of the analysis was to assess the relevance of the collected data in order to understand the risk of systemic colonization associated with these devices, while acknowledging their well-established benefits.

Ethical Considerations

The Institutional Review Board of the Department of Medicine at the University of Udine (protocol 15/2024, Title III class 13 file 209/2024) approved this study. Given the retrospective design of this study, the requirement for informed consent was waived, and an opt-out approach was utilized instead.

Results

During the 8-month study period, from January to August 2023, a total of 91 devices were placed. However, only the tips of 50 devices were sent for culture analysis; therefore, only these 50 cases were included in the present analysis (Table 1). Among these, the most frequently implanted device type was the mini-midline inserted using the Seldinger technique ($n = 37$; 74.0%), followed by the "All-in-One" mini-midline ($n = 12$; 24.0%), and, in one case ($n = 1$; 2.0%), a midline catheter.

The indication for device placement differed by device type. The decision to place either an "All-in-One" mini-midline or a mini-midline using the modified Seldinger technique was based on the operator's confidence with the procedure and the availability of supplies in stock. Among patients who received the "All-in-One" mini-midlines, 7 out of 12 (58.3%) were treated for the need of multiple drug administrations and/or frequent blood draws. Conversely, 22 out of 38 patients (57.9%) who received either Seldinger-placed mini-midlines or the single midline had poor venous access. Most of the devices were equipped with a dual-

lumen extension ($n = 42$; 84.0%). This is an accessory that provides two separate channels (lumens) for infusions, allowing simultaneous administration of different fluids or medications through a single vascular access point. In the majority of cases, a standard dressing was used at the exit site ($n = 35$; 70.0%). This a secure, low-profile adhesive dressing that stabilizes the device while keeping the exit site visible for monitoring (GAVeCeLT, 2024). Only 6 out of 50 devices (12.0%) were removed due to suspected infection, with symptoms including fever, chills, elevated white blood cell count, and signs of systemic inflammation at the time of assessment. However, none of them tested positive on culture. Of the 6 devices removed, the only tip that tested positive in the aforementioned examination was a Seldinger-technique-placed mini-midline in a patient undergoing numerous infusions and/or blood draws from the same device. It was removed after 12 days due to discontinued utility (Table 2). The majority of the remaining devices were removed due to discontinued utility ($n = 31$; 62.0%), followed by those removed for occlusion/dysfunction ($n = 9$; 18.0%), and finally, those removed due to displacement/outside the vein ($n = 4$; 8.0%). The overall median dwell time for the devices was 11.50 days [IQR 7.00 – 16.00 days]. At the time of removal, the exit site showed no signs of inflammation in 42 devices (84.0%), while the remaining devices showed visible redness and swelling < 1 cm around the exit site. A higher proportion of patients receiving "All in One" devices were treated with multiple medications or received frequent blood draws (58.3%) compared to those receiving other devices for poor venous access (57.9%). According to the Visual Exit Site Score (VESS), most devices (84.0%) showed a score of 0, while 16.0% had mild redness < 1 cm (score 1).

Discussion

Our study reached similar conclusions to those in the literature. Ultrasound-guided mini-midlines have shown better performance than traditional PIVs, especially in patients with poor venous access (Badger, 2019; Qin et al., 2021). This device appears to lower the risk of complications such as thrombophlebitis, extravasation, and site infections (Scoppettuolo et al., 2016). In both our study and that by Qin K. R. et al. (2021), most mini-midlines (62.0% and 73.1%, respectively)

Table 1. Classification of results based on the positioned device (part 1).

Patient characteristics	“All in one” Mini-midline n = 12 (100.0%)	Mini-midline Seldinger technique or Midline n = 38 (100.0%)	p-Value
Years, media [± SD]	60.25 [± 13.46]	62.53 [± 17.55]	0.682
Male sex, n (%)	11 (91.7)	23 (60.5)	0.074
Weight (Kg), median [IQR]	73.50 [57.75 – 81.50]	75.00 [59.25 – 81.50]	0.532
Height (m), media [± SD]	1.73 [± 0.07]	1.71 [± 0.09]	0.612
BMI, median [IQR]	23.30 [21.40 – 25.77]	24.30 [21.83 – 29.33]	0.658
Patient arriving from, n (%):			
Emergency department	6 (50.0)	15 (39.5)	0.904
Other hospital department	2 (16.7)	9 (23.7)	
Home	2 (16.7)	9 (23.7)	
Intensive Care Unit (ICU)	2 (16.7)	5 (13.1)	
Reason for hospitalization, n (%):			
Bacterial infection	9 (75.0)	31 (81.6)	0.388
Viral infection	2 (16.7)	7 (18.4)	
Infection of another origin	1 (8.3)	0 (0.0)	
Fungal infection	0 (0.0)	0 (0.0)	
Type of hospitalization, n (%):			
Ward	11 (91.7)	34 (89.5)	1.000
Day hospital	1 (8.3)	4 (10.5)	
Medical history, n (%):			
Cardiovascular diseases	7 (58.3)	23 (60.5)	1.000
Endocrine, nutritional or metabolic diseases	5 (41.7)	21 (55.3)	0.514
Immunological diseases	4 (33.3)	11 (28.9)	1.000
Neurological, mental or behavioral diseases	3 (25.0)	12 (31.6)	1.000
Musculoskeletal diseases	3 (25.0)	12 (31.6)	1.000
Hematological diseases	3 (25.0)	10 (26.3)	1.000
Gastrointestinal diseases	5 (41.7)	8 (21.1)	0.256
Oncological diseases	4 (33.3)	9 (23.7)	0.707
Respiratory diseases	2 (16.7)	10 (26.3)	0.705
After device placement			
Reason for device placement, n (%):			
Poor venous access	3 (25.0)	22 (57.9)	0.055
Numerous infusions and/or blood tests	7 (58.3)	15 (39.5)	
Other reasons	2 (16.7)	1 (2.6)	
Days of hospitalization before device placement, median [IQR]	2.50 [1.00 – 6.00]	3.50 [1.00 – 11.00]	0.373
Number of times the patient was punctured for device placement, median [IQR]	1.00 [1.00 – 1.00]	1.00 [1.00 – 1.00]	0.550
Use of ultrasound for placement, n (%):			
Yes	11 (91.7)	38 (100.0)	0.240
No	1 (8.3)	0 (0.0)	
Patient's dominant arm, n (%):			
Right	12 (100.0)	37 (97.4)	1.000
Not evaluable	0 (0.0)	1 (2.6)	
Left	0 (0.0)	0 (0.0)	
Arm in which the device was placed, n (%):			
Left	6 (50.0)	22 (57.9)	0.743
Right	6 (50.0)	16 (42.1)	

Table 1. Classification of results based on the positioned device (part 2).

Patient characteristics	“All in one” Mini-midline n = 12 (100.0%)	Mini-midline Seldinger technique or Midline n = 38 (100.0%)	p-Value
Site of device placement, n (%):			
Arm	8 (66.7)	38 (100.0)	0.002
Forearm	4 (33.3)	0 (0.0)	
Type of connector applied to the device, n (%):			
Dual-lumen extension (Octopus)	12 (100.0)	30 (78.9)	0.173
Needle free connector	0 (0.0)	9 (23.7)	0.092
Type of dressing applied to the device, n (%):			
Basic	11 (91.7)	24 (63.2)	0.079
With chlorhexidine patch	1 (8.3)	14 (36.8)	
Experience of the nurse who implanted the device (years of work), median [IQR]	3.00 [2.75 – 4.25]	12.00 [2.25 – 12.00]	0.125
After device removal			
Exit-site (according to the Visual exit-site score), n (%):			
Intact, healthy skin	10 (83.3)	32 (84.2)	1.000
Reddening < 1 cm around exit-site (± fibrin)	2 (16.7)	6 (15.8)	
Reddening > 1 cm around exit-site (± fibrin)	0 (0.0)	0 (0.0)	
Reddening, secretion and pus (± fibrin)	0 (0.0)	0 (0.0)	
Duration in place (days), median [IQR]	9.50 [6.00 – 14.25]	12.00 [7.25 – 17.75]	0.363
Main reason for removal, n (%):			
Discontinued utility	10 (83.3)	21 (55.3)	0.132
Occlusion and/or malfunction	0 (0.0)	9 (23.7)	
Suspected infection	2 (16.7)	4 (10.5)	
Displacement and/or device out of vein	0 (0.0)	4 (10.5)	
Use, n (%):			
Administration of antibiotics and/or antivirals and/or antifungals and/or other antimicrobials	10 (83.3)	34 (89.5)	0.621
Blood tests	10 (83.3)	32 (84.2)	1.000
Administration of blood and/or blood products	3 (25.0)	8 (21.1)	1.000
Administration of parenteral nutrition (partial and/or total)	0 (0.0)	2 (5.3)	1.000
Culture result (tip), n (%):			
Negative	12 (100.0)	37 (97.4)	1.000
Positive	0 (0.0)	1 (2.6)	

Legend: n: absolute frequency; %: relative percentage frequency; SD: Standard Deviation; IQR: Interquartile Range; BMI: Body Mass Index.

were removed due to completion of intravenous therapy. Regarding infections, findings across the literature are consistent: mini-midlines appear to be safe devices, with low CRBSI rates reported—0.72 (Fabiani et al., 2020) and 0.96 per 1000 catheter-days (Fabiani et al., 2017). One study recorded only a single CRBSI event (Fabiani et al., 2017), and another reported no infectious complications at all (Scoppettuolo et al., 2016). In both Qin K. R. et al. (2021) and our study, most mini-midlines (73.1% and 62.0%, respectively) were removed after completing therapy. Regarding infections, the literature consistently supports the safety of mini-

midlines, with low CRBSI rates of 0.72 (Fabiani et al., 2020) and 0.96 per 1000 catheter-days (Fabiani et al., 2017). Notably, one study reported only a single CRBSI episode (Fabiani et al., 2017), while another found none (Scoppettuolo et al., 2016). However, it is not possible to make a direct comparison with our study regarding this topic for several reasons: firstly, due to the definition of CRBSI. This is defined as a primary bloodstream infection directly attributable to an intravascular catheter, confirmed by matching pathogens cultured from the catheter and blood samples, indicating the catheter as the infection source (O'Grady et al., 2009). Secondly, regarding

Table 2. Outcome of the single positive culture examination with patient characteristics.

Culture outcome	
Type	Staphylococcus Epidermidis (MLSb phenotype, methicillin-resistant)
Bacterial charge	1400 CFU/mL
Resistant to (MIC value)	Erythromycin (> 4), gentamicin (> 4), levofloxacin (2), oxacillin (2), moxifloxacin (0.5)
Sensitive to (MIC value)	Trimethoprim-sulfamethoxazole (1), linezolid (< 1), teicoplanin (0.5), doxycycline ($\leq$ 0.5), vancomycin ($\leq$ 0.5), fusidic acid ($\leq$ 0.25), daptomycin ($\leq$ 0.25), tigecycline ($\leq$ 0.125), rifampicin ($\leq$ 0.0625)
Patient characteristics	Male, 49 years old. BMI 22 (60 kg x 1.65 m). Coming from another department and admitted for bacterial infection. Endocrine, nutritional or metabolic diseases in medical history. Five days after admission, a Seldinger-technique mini-midline was placed on the left arm (dominant arm: right) for numerous infusions/blood tests. Two attempts were made to place it. A dual-lumen extension (octopus) was connected to the device, and a simple dressing was applied. After 12 days, the device was removed due to discontinued utility. The exit site of the device showed no signs of inflammation and the surrounding skin was intact. The device was used for blood tests, administration of antimicrobials and blood/ blood products transfusions.

the incidence rate of the phenomenon. Our study only evaluated the positivity of the culture examination conducted on the tip of the device once removed, calculating the percentage of results. This is certainly a significant limitation as we cannot affirm the presence of CRBSI but only the potential colonization of the catheter, which occurred in 1 case out of 50 (2.0%). Moreover, signs of infection such as fever or an increase in inflammatory markers were not detected. However, since the only positive result was *Staphylococcus epidermidis*, a common skin commensal (O'Grady et al., 2002), we cannot be certain whether this reflects true catheter colonization or sample contamination. It is also noteworthy that from the classification performed, overall, no statistically significant differences emerged between those devices placed in a clean environment (mini-midline "All in one") and those placed in a sterile environment (the remaining mini-midlines and the midline) since just one tip tested positive.

Limits of the study

This study has several limitations. First, its retrospective and monocentric design may limit the generalizability of findings. Second, the sample size was relatively small, and the number of midlines included was insufficient for proper comparison with mini-midlines. Third, the absence of data from other vascular access devices (e.g., PIVs or PICCs) precludes meaningful comparisons. Furthermore, although catheter tip cultures were analyzed, no differential time to positivity (DTP) was performed, limiting the ability to confirm catheter-related bloodstream infections (CRBSI). Some devices could not be

used for blood sampling due to occlusion, making DTP technically unfeasible. Finally, no data were collected on clinical signs or symptoms (e.g., fever, chills, inflammatory markers) to correlate colonization with clinical infection.

Another limitation of this study is the inability to directly compare the results with other vascular accesses, such as PIVs or central lines (e.g., Peripherally Inserted Central Catheters), since these were not included. Comparisons were therefore possible only using data available from the literature. The small sample size and the study's design also certainly influenced the results. In conclusion, future studies should include a greater number of midlines to enable a direct comparison with mini-midlines.

Conclusion

Mini-midlines appear to be valid and safe devices for patients requiring short-term intravenous therapy and for those with poor venous access. However, given the numerous limitations of this study, further research is needed to more adequately explore the topic.

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Improper Access to the Emergency Department: Development and Validation of a Tool

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Abstract

Introduction. The main purpose of the Emergency Department (ED) is to treat emergency and urgent cases requiring immediate assistance through rapid diagnosis and timely medical or surgical intervention. However, citizens may perceive the ED as a solution for all health and social issues, leading to inappropriate visits. This critical phenomenon has recently been highlighted at the international level due to the potential negative consequences. The underlying causes of inappropriate ED use are still not clearly understood. This study aims to provide a tool to identify the underlying reasons for inappropriate ED visits.

Methods and materials. Multi-phase study. Phase 1: narrative literature review to identify domains and develop specific items; Phase 2: content validation by a panel of experts; Phase 3: face validation by an additional group of professionals. Phase 4: translation by bilingual experts.

Results. A total of 21 items were developed, distributed across 4 domains, plus a section to be completed by the administrator. The content validity index of individual items (I-CVI) ranged from 0.80 to 1.00; the scale content validity index (S-CVI) of the questionnaire was 0.98. The final version of the questionnaire achieved an average face validity score of 3.90 (± 0.32) on a 4-point scale.

Discussion. Non-urgent ED use is considered an indicator of healthcare system efficiency. This study offers the scientific community a useful tool to explore the motivations behind inappropriate ED use, with particular attention to the knowledge of territorial services, perceived urgency, and trust in healthcare professionals. This type of study can inform the development of strategies to address inappropriate ED use and to evaluate the effectiveness of

community-based services. Larger, prospective studies are warranted to further confirm the safety profile of these devices.

Keywords: Inappropriate Use, ED, Questionnaire, Nurse, Psychometric Validation

Introduction

The main purpose of the Emergency Department (ED) is to treat emergency and urgent cases that require immediate assistance through rapid diagnosis and timely medical or surgical treatment (Sartini et al., 2022). However, this service can be perceived by citizens as the solution for all health and social problems, leading to ED visits for non-urgent cases and therefore potentially inappropriate access (Bonetti & Melani, 2019).

For years, the scientific community has debated the definition of “inappropriate” or “unwarranted” ED visits, due to the equivalence often made between non-urgency and inappropriateness of access (Honigman et al., 2013; Mengoni & Rappini, 2007; Mistry et al., 2008). In this study, we adopted the definition provided by Bianco (2003), according to which an ED visit is considered inappropriate if it is non-urgent and could be more appropriately managed by other territorial healthcare facilities (Bianco et al., 2003).

Inappropriate visits are one of the main contributors to overcrowding (Bahadori et al., 2020), defined as a situation in which the normal operation of the ED is hampered by a mismatch between healthcare demand—represented by the number of patients waiting and being treated—and the logistical, instrumental, and professional resources available (Ministry of Health & General Directorate for Health Planning, 2019).

This phenomenon, internationally known as overcrowding, has become a serious healthcare issue, worsened by the reduction in the number of EDs and the increase in patients requiring emergency services (Carter et al., 2014). Various studies agree on the high prevalence rates of inappropriate ED use, estimated between 20% and 40% (Carret et al., 2009).

In Italy, overcrowding represents a daily challenge for healthcare professionals (Belardinelli et al., 2024). Overcrowding is a

complex and multifactorial phenomenon (Salway et al., 2017), essentially characterized by three factors: input (volume of incoming patients), throughput (time needed to process and treat patients), and output (volume of patients leaving the ED) (Badr et al., 2022).

Although many studies have specifically examined the factors influencing non-urgent ED use, it remains difficult to draw meaningful conclusions about patients’ reasons due to methodological differences, study designs, quality assessments, and synthesis approaches. Moreover, most studies have been published in high-resource countries such as the United States, the United Kingdom, Canada, and Australia. Therefore, the understanding of non-urgent ED use in lower-resource countries is still limited (Bahadori et al., 2020; McIntyre et al., 2023).

According to McIntyre et al. (2023), further investigation is needed in areas that would help fill the knowledge gaps about inappropriate ED use and address methodological issues. The authors argue that health literacy, emotions, beliefs, attitudes, and behavioral response models influence decision-making, particularly concerning the perceived severity and urgency of a condition.

Morgans & Burgess (2011) also point out that psychosocial factors such as stress and coping abilities have been explored in only a limited number of studies, mostly as an afterthought (Morgans & Burgess; 2011). New research should explicitly assess health literacy, personal health beliefs, stress, and coping capacity using validated outcome measures (McIntyre et al., 2023).

In Italy, several studies have addressed the issue using ad hoc questionnaires developed with reference to the specific healthcare services available in the respective geographic areas, making them less generalizable to the national context. There is a lack of validated tools in the literature, based on scientific evidence, that provide reliable data on the motivations behind this phenomenon in the Italian context.

Based on these reflections, the authors aimed to develop a tool grounded in the most recent

scientific evidence, in the form of a questionnaire to be administered to users accessing the ED for non-urgent conditions, with the goal of identifying their motivations.

The main objective of this study is the development and validation—both content and face—of a tool designed to investigate the motivations behind inappropriate access to the Emergency Department. The tool aims to explore users' level of knowledge, self-perception of urgency, and the social recognition of the nurse's role in meeting healthcare needs related to ED access.

Methods and Materials

A multi-method, multi-phase study was conducted. The first phase focused on tool development; the second phase assessed the content validity of the questionnaire; the third phase examined the face validity of the final instrument.

Working Group

For each phase of the study, a dedicated working group was formed based on the specific needs of that phase.

Phase One: Identification of Domains

To investigate the phenomenon of inappropriate ED access, a narrative, non-systematic literature review was carried out by AC and VD, aimed at identifying the specific items for questionnaire development (Green et al., 2006). A total of 19 items were created (the demographic section was considered as a single item), grouped into five domains: demographics; reasons for access; knowledge; social recognition of the nurse; and a section to be completed by the administrator.

Items in the 'Social recognition of the nurse' domain were expanded based on recent organizational models in which nurses are assigned greater autonomy and competence than in the past.

Phase Two: Content Validity

Content validity reflects how well the elements of an assessment tool are relevant and representative of the intended construct—i.e., how completely and appropriately they explore the subject under study (Yusoff, 2019).

Establishing content validity is essential to

support the validity of a tool and the results it yields. Haynes et al. (1995) emphasize that "Inferences from assessment tools with inadequate content validity will be questionable, even if other indicators of validity are satisfactory."

A panel of 10 experts—4 physicians and 6 nurses from Umbria, Emilia-Romagna, Sicily, Campania and Sardinia—was assembled to evaluate the content validity. This geographic diversity was intended to ensure adaptability of the tool across different regional healthcare systems. Experts were selected based on their experience in emergency healthcare, with selection criteria including:

a) at least 5 years of experience in emergency care (either in ED or territorial emergency services);

b) at least one postgraduate qualification, such as a Master's in Critical Care or a Master's Degree (for nurses).

The questionnaire was shared with the panel in February 2024. Experts were asked to rate the relevance of each item based on appropriateness and adherence to the study using a four-point Likert scale (1 = strongly disagree; 2 = disagree; 3 = agree; 4 = strongly agree), following Yusoff's (2019) methodology (Yusoff, 2019).

All items except those in the demographic section were evaluated for content validity. The Content Validity Index (CVI) was calculated for each item (I-CVI) and for the entire questionnaire (S-CVI). I-CVI was calculated as the number of experts rating an item as relevant (Likert 3 or 4) divided by the total number of experts. With ten experts, an I-CVI ≥ 0.78 was considered acceptable (Yusoff, 2019). The S-CVI was derived from the average I-CVI values (S-CVI/Ave). An S-CVI > 0.8 was considered acceptable (Yusoff, 2019).

Phase Three: Face Validity

Face validity refers to the qualitative (subjective) assessment of how suitable an instrument appears to be for measuring the intended concept. It is a superficial estimation based on the immediate impression of appropriateness (Elangovan & Sundaravel, 2021).

An additional group of experts was formed for this phase, consisting of 1 physician and 4 nurses from different regions (Umbria, Lazio, Campania e Sicily), all with experience in critical care units. The nurses had at least a first-level Master's

degree in Critical Care or a Master's degree.

The questionnaire was administered to the expert group, and to ensure a methodical process, they were asked to evaluate each item based on adequacy, clarity, completeness, and neutrality, assigning a score from 1 (minimum) to 4 (maximum).

Phase Four: Translation

The questionnaire was translated into English, French, Spanish, and Arabic through a process involving bilingual experts, with particular attention to the cultural adaptation of the items.

Ethical Considerations

The questionnaire included in this study was submitted to the Ethics Committee of the Umbria Region and received approval for administration (No. CE-743/24, 17/04/2024). The committee also recommended offering the tool in multiple languages, which is reported in phase 4 in the methods section.

Results

Content Validity

The content validity scores for individual items ranged from 0.80 to 1.00. Experts gave

Table 1. Excel worksheet used to calculate Content Validity Index.

	Sicily	Sardegna	Campania	Umbria	Umbria	Sardegna	Sardegna	Emilia Rom.	Emilia Rom.	Umbria	Experts in		
	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9	Expert 10	Agreement	I-CVI	UA
Item													
Q1	1	1	1	1	1	1	1	1	1	1	10	1	1
Q2	1	1	1	1	1	1	1	1	1	1	10	1	1
Q3	1	1	1	1	1	1	1	1	1	1	10	1	1
Q4	1	1	1	1	1	1	1	1	1	1	10	1	1
Q5	1	1	1	1	1	1	1	1	1	1	10	1	1
Q6	1	1	1	1	1	1	1	1	1	1	10	1	1
Q7	1	1	1	1	1	1	1	1	1	1	10	1	1
Q8	1	1	1	1	1	1	1	1	1	1	10	1	1
Q9	1	1	1	1	1	1	1	1	1	1	10	1	1
Q10	1	1	1	1	1	1	1	1	1	1	10	1	1
Q11	1	1	1	1	1	1	1	1	1	1	10	1	1
Q12	1	1	1	1	1	1	1	1	1	1	10	1	1
Q13	1	1	1	1	1	0	1	1	1	0	8	0,8	0
Q14	1	1	1	1	0	1	1	1	1	1	9	0,9	0
Q15	1	1	1	1	1	1	1	1	1	1	10	1	1
Q16	1	1	1	1	1	1	1	1	1	1	10	1	1
Q17	1	1	1	1	1	1	1	1	1	1	10	1	1
Q18	1	1	1	1	1	1	1	1	1	1	10	1	1
Q19	1	1	1	1	1	1	1	1	1	1	10	1	1
											S-CVI/Ave	0,98	
Proportion relevance	1	1	1	1	0,95	0,95	1	1	1	0,95	S-CVI/UA		0,89
Average proportion of items judged as relevance across the experts												0.98	

Legend: Q = Question; CVI = content validity index; UA = universal agreement; I - CVI = individual - level content validity index; S - CVI/Ave = scale-level content validity index based on the average method; S - CVI/UA = scale-level content validity index based on the universal agreement method.

unanimous agreement (universal agreement, S-CVI-UA) for 17 out of 19 items (89.4%). The overall scale content validity index (S-CVI/Ave) was 0.98, indicating excellent relevance in relation to the questionnaire's research objective. Table 1 summarizes the I-CVI and S-CVI scores.

Face Validity

The face validity evaluation yielded an average score of 3.90 ($\pm$ 0.32). None of the items in the final version raised significant concerns; thus, the experts agreed that no modifications were needed. Scores ranged from 3 to 4 on a 1–4 scale, both for individual items and the overall tool, indicating good quality (Table 2).

Table 2. Overall scores of the face validation

	Score ($\pm$ SD)
Pertinence	3,90 ($\pm$ 0,35)
Clarity	3,94 ($\pm$ 0,23)
Understandability	3,89 ($\pm$ 0,30)
Neutrality	3,88 ($\pm$ 0,40)
Overall score	3,90 ($\pm$ 0,32)

Legend: SD = standard deviation.

Discussion

The use of the ED for non-urgent care is often seen as an indicator of inadequate primary healthcare (Booker et al., 2015). This

phenomenon can negatively affect patients, healthcare providers, and the healthcare system as a whole (Bahadori et al., 2020).

Understanding the subjective motivations and psychosocial factors that influence user behavior is essential to addressing the issue of overcrowding. This is particularly relevant in Italy, where 23% of the population is over 65 years old (Italian Government, 2021), and chronic conditions are increasingly prevalent. Older adults are at high risk of complications and exacerbations, making them frequent users of emergency services (Longhini et al., 2023).

This study led to the development of a validated tool capable of objectively and thoroughly exploring the motivations that prompt users to access the ED for non-urgent conditions. The questionnaire underwent a rigorous process of content and face validation, demonstrating strong ability to capture key factors associated with inappropriate access.

A central issue raised is the motivations behind low-priority ED visits. Although several international studies have addressed this phenomenon (McIntyre et al., 2023), most focus on high-income countries with limited attention to national or resource-limited settings. In Italy, previous research has been region-specific and not always based on rigorous scientific criteria. This knowledge gap prompted the creation of a standardized, validated questionnaire to explore these motivations.

The high I-CVI and S-CVI scores confirm the tool's reliability and relevance (Haynes et al., 1995). A key factor is users' health literacy and subjective perception of urgency. As noted by McIntyre et al. (2023), patients' perception of their condition's severity plays a crucial role in their decision to go to the ED. Improving public awareness and information about community health services could reduce the tendency to view the ED as the only solution, even for non-urgent issues.

Although the validation processes included experienced physicians and nurses working in six different regions, the evaluations may not fully represent the Italian territory, characterized by a large geographical extension and local health services organized differently.

Study Limitations

Although the questionnaire was developed with consideration for the regional heterogeneity

of the Italian healthcare system, the experts involved in the content validation process were drawn from only five Italian regions. This limited geographic representation may have affected the generalizability of the instrument.

Another limitation is the lack of involvement of the study's target users in the evaluation process.

Finally, the tool requires further testing to assess its generalizability and adaptability to settings other than Italy, as well as to different levels of health literacy.

Practical Implications and Future Perspectives

The results of this study offer valuable insights for improving the management of inappropriate ED access and may inform public health policies. The validated questionnaire may serve as a basis for broader studies involving larger populations to generate representative and objective data that could facilitate regional comparisons. Furthermore, the information gathered can guide targeted interventions to reduce inappropriate access and ED overcrowding by improving awareness, health education (Williams & Haffizulla, 2021), access to community services, and the recognition of the nurse's role.

The nurse has proven effective in reducing inappropriate ED use through innovative models such as See & Treat (Di Nardo et al., 2023), Process Nurse (Belardinelli et al., 2024), and integrated home care (Campagna et al., 2022). Future studies should explore larger, more diverse samples to validate the tool in various healthcare settings.

According to McIntyre et al. (2023), additional studies should use validated outcome measures to investigate the role of psychosocial factors influencing decision-making, including health literacy, personal health beliefs, stress, and coping skills.

Each region could simulate scenarios like the one presented here to evaluate how a management model for low-priority emergencies could alleviate ED overcrowding.

Conclusions

Understanding the motivations behind inappropriate ED access is essential for developing effective overcrowding management strategies, which has financial and operational consequences for users, staff, and the healthcare system (Annese et al., 2019).

The questionnaire developed in this study offers a new investigative approach to collect data useful for improving health policy, particularly in terms of health education and public perception of urgency.

Assessing the perception of various healthcare roles—especially that of nurses—may help better understand how patients view healthcare personnel's role in managing their health. Understanding the social recognition of nurses could promote their professional visibility and inform the curriculum of future clinical master's degree programs.

Offering the questionnaire in multiple languages allows the exploration of differences between local and non-Italian users.

The validated questionnaire is a significant first step toward better understanding this phenomenon and improving the effectiveness and efficiency of emergency healthcare services.

The presented paper will be followed by a multicenter pilot study involving a large sample of users.

Future research could enhance the tool's effectiveness by testing it in broader and more varied contexts, contributing to a more efficient and appropriate use of emergency healthcare resources.

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Nurse Competence Scale: A Multicenter Observational Study on Nursing Competencies in Northern Italy

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Abstract

Introduction. Nursing competence—encompassing knowledge, skills, and experience—is key to delivering safe, high-quality care. Self-assessment supports professional growth, enhances satisfaction, and may lower turnover. This study aimed to assess nurses' self-declared competencies across four domains (management, nursing care, leadership, and ethics) using the validated Italian Nurse Professional Competence Scale–Short Form (I-NPCS-SF).

Methods. A multicenter cross-sectional study was conducted on 161 nurses from two hospitals in Northern Italy (Oct–Dec 2024). Data were analyzed with ANOVA using Jamovi.

Results. Higher scores were found in all areas. Postgraduate education and 6–10 years' experience correlated with better scores.

Discussion. Assessing nursing competencies is essential to maintain care quality and guide professional development. Promoting regular self-assessment helps identify areas for growth, supports career progression, and contributes to nurse retention.

Keywords: Leadership, Nursing Competence, Professional Development, Quality of Care, Self-Assessment

Introduction

Today's healthcare is rapidly evolving due to emerging diseases, an aging population, low birth rates, diverse patient needs, and technological advancements (Karami et al., 2017). These complex dynamics challenge all healthcare professionals, including nurses, who must continuously develop their competencies to ensure patient safety, high-quality care, and improved outcomes (Fukada, 2018). Despite being widely discussed, the concept of competence remains ambiguous (Garside & Nhemachena, 2013; Smith, 2012). A standardized definition is essential to strengthen the nursing profession's identity (Yanhua & Watson, 2011). Benner defines competence as performance described through intent, function, and meaning—not merely task execution (Benner, 1982). Others define it as a combination of knowledge, skills, attitudes, and abilities aimed at achieving organizational goals (Audenaert et al., 2014; Dellai et al., 2009; Gunawan & Aunguroch, 2017). Competence is acquired and maintained over time as part of a broader effort to ensure quality (Mayo et al., 2018).

Research links higher patient satisfaction to nurses' competencies, especially technical and relational skills (Kozka et al., 2019; Tomaszewska et al., 2023). Competence is now recognized as fundamental to care outcomes (Bing-Jonsson et al., 2016; Maheu et al., 2020), though factors influencing it—such as experience, age, work environment, employment status, self-esteem, satisfaction, and critical thinking—show inconsistent associations (Kim & Choi, 2019; Kim & Kim, 2015; Liu & Aunguroch, 2018; Meretoja et al., 2004; Numminen et al., 2016).

Nurses must develop professional competencies to meet growing and complex care demands (AllahBakhshian et al., 2017; Helminen et al., 2016). Competence can be measured through outcomes sensitive to nursing care, including medication errors, patient falls, infections, complaints, pressure ulcers, cardiac arrests, and deaths, standardized per patient-days or medication doses (Twigg et al., 2019). Its assessment is complex, involving various dimensions observed during both training and daily practice (Cai, 2016; Halcomb et al., 2016; Lin et al., 2017). Increased competence

is expected to reduce adverse events, but reliable, valid, and sensitive tools are needed to measure it accurately (Streiner et al., 2015). Self-assessment scales promote professional development, job satisfaction, and may reduce turnover, improving care quality (Dellai et al., 2009). In Italy, literature on this topic remains limited (Emanuela et al., 2023; Notarnicola et al., 2018; Notarnicola et al., 2024; Prendi et al., 2022), highlighting the need for research tailored to the national context.

This study aims to investigate self-perceived competencies among nurses in four factors—management, nursing care, leadership, and ethics—using the Italian version of the Nurse Professional Competence Scale – Short Form (I-NPCS-SF) (Emanuela et al., 2023).

Methods

Design

A multicenter cross-sectional study was conducted between October and December 2024 at two hospital facilities in northern Italy. The study followed the STROBE guidelines for observational studies (von Elm et al., 2007). (Supplementary File 1).

Population and sample

The study population consisted of employed nurses and freelance professionals working in operating units of the medical area (internal medicine, specialized medicine, long-term care), the surgical area (general surgery, specialized surgery, orthopedics and traumatology), the rehabilitation area, and the critical area, day hospital nurses (medical/oncological – surgical), nurses working in outpatient services/sample collection centers, and diagnostic areas (e.g., radiology, endoscopy), as well as territorial services.

The study included shift nurses and nurses working day shifts, performing clinical activities, with a Bachelor's Degree in Nursing or equivalent qualifications, Postgraduate Certificate, MSc in Nursing, Postgraduate Diploma, and Doctor of Philosophy (PhD) in Nursing, with no limits on total work experience or experience in the department at the time of the study. Both full-

time and part-time nurses were included.

Nurses with roles in coordination, management, research, or training, as well as those not involved in direct clinical activities, were excluded from the study.

Setting

The study was conducted at a public hospital facility and a private hospital facility in northern Italy.

Instruments

For the assessment of nursing competencies, the I-NPCS-SF was used, a shortened version of the Nurse Professional Competence Scale originally developed by Nilsson et al. (2014) and later validated in several international contexts (Gardulf et al., 2016; Nilsson et al., 2018; Van de Mortel et al., 2021).

The Italian version of the I-NPCS-SF, validated by Emanuela et al. (2023), is a valid and reliable tool for measuring nurses' professional competence.

The scale is based on Benner's competence framework (Benner, 2003) and consists of 35 items divided into four factors: Management, Acts, Leadership, and Ethics (Supplementary File 2).

The Management factor concerns the management of care, focusing on safety, technology, interprofessional collaboration, and evidence-based practices.

Acts explores clinical competencies, including medication management, patient monitoring, and safety of care. Leadership focuses on empathetic communication and psychological support for bennerpatients from a holistic perspective.

Ethics reflects ethical competence, emergency management, and the nurse's role in supervision.

Responses are provided on a seven-point Likert scale, ranging from 1 (very low) to 7 (very high), based on the nurse's level of agreement with each statement. For the use of the I-NPCS-SF in this cross-sectional study, authorization was obtained from corresponding author Notarnicola.

Data collection

The data collection was carried out between October and December 2024.

It involved the anonymous completion

of the I-NPCS-SF tool, administered via the Microsoft Forms application by the assigned researcher, following approval from the General Management and with the collaboration of the nursing coordinators from all the enrolled facilities.

Participants were sent an invitation via email from the project leader and/or a team member familiar with the contact, followed by several reminders approximately every three weeks.

The email invitation contained information about the study, and after consent to participate, a link to the survey.

Data analysis

Data were analyzed using Jamovi software (The jamovi project, 2024). At the end of the data collection, a statistical analysis of the demographic variables considered was conducted, representing and summarizing the sample characteristics with absolute values and frequencies. The mean and standard deviation were calculated for each factor in relation to the different demographic characteristics examined.

The results of the competence scale by factors were summarized following the calculation formulas provided by the authors of the Italian validation of the scale (Emanuela et al., 2023) (Supplementary File 2).

Finally, the mean competence scores were compared between the different demographic variables, such as age range, gender, educational background, total years of work experience, contract type and profile, work schedule, and work area, using Welch's one-way ANOVA.

Ethical Considerations

The study was submitted for acknowledgment to the university board and registered under protocol number CLM.24.01. The study was conducted in accordance with the Declaration of Helsinki (World Medical Association, 2024).

Written information explaining the study's purpose was provided to potential participants (Supplementary File 3).

Informed consent and data processing was obtained from all participants before their involvement.

Participants were informed that joining was voluntary and that the study results would not affect their employment.

Results

Participants

The study included a total population of 161 nurses, with 96 questionnaires returned from the private hospital facility and 65 from the public hospital facility.

Regarding the entire sample, the most represented age group was 20-30 years, which accounted for 34% of the total.

The female group represented 78% of the sample. In relation to the operational unit of affiliation, 25% of nurses were assigned to the critical care area, followed by the surgical area (17%), territorial services (16%), medical area (16%), outpatient services (13%), diagnostic area (5%), rehabilitation area (5%), and day hospital (3%).

The most represented level of education was the Bachelor's Degree in Nursing (47%). Forty-six nurses held a Postgraduate Certificate (28%), four nurses held a MSc in Nursing (2%), one nurse had completed a Postgraduate Diploma (1%), and no nurse had a PhD.

Additionally, 96% of the total sample were employed by the institution, with 94% holding a full-time contract and 60% reporting working in shifts.

Work experience in years was distributed as follows: <1 year (5%), 1-5 years (23%), 6-10 years (19%), 11-20 years (20%), 21-30 years (16%), >30 years (17%).

These demographic data are presented in Table 1, along with the absolute numbers and percentages.

Between the public and private facilities, the following demographic differences emerged: the nurses' age was higher in the public facility (34% over 50 years old) compared to the private facility (50% between 20-30 years old), which is reflected in the years of service, with 34% in the public facility having 11-20 years of service and 32% in the private facility having 1-5 years. No nurse in the public hospital facility had less than one year of service. The most common level of education in the public facility was a Postgraduate Certificate (38%), whereas in the private facility, it was the Bachelor's degree (58%).

Regarding the operational unit of affiliation, 40% of nurses in the public context worked in territorial services, and 57% reported working day shifts, while in the private facility, 28%

Table 1. Characteristics of study participants .

Variables		Absolute	Frequency
Operating Unit	Surgical Area	28	17%
	Critical Area	40	25%
	Diagnostic Area	8	5%
	Medical Area	26	16%
	Rehabilitation Area	8	5%
	Day Hospital	4	3%
	Outpatient Services	21	13%
	Territorial Services	26	16%
Gender	Female	126	78%
	Male	34	21%
	Not Declared	1	1%
Age Range	20-30 years	55	34%
	31-40 years	37	23%
	41-50 years	33	21%
	>50 years	36	22%
Education Level	Nursing Diploma	35	22%
	Bachelor's Degree in Nursing	75	47%
	Postgraduate Certificate	46	28%
	Master's in Nursing Sciences	4	2%
	Postgraduate Diploma	1	1%
	PhD	0	0%
Work Experience	<1 year	8	5%
	1-5 years	37	23%
	6-10 years	31	19%
	11-20 years	33	20%
	21-30 years	25	16%
	>30 years	27	17%
Contract Type	Employee	155	96%
	Freelancer	6	4%
Contract Profile	Full-time	151	94%
	Part-Time	10	6%
Work Schedule	Day Worker	65	40%
	Shift Worker	96	60%

worked in the critical care area, and 71% worked in shifts.

Competence

The aggregated results in the four factors—Management, Nursing, Leadership, and Ethics are described. Nurses assigned high average scores across all factors.

The data suggest that, in general, the responses for all factors and for both public and private

settings are quite similar, with few significant differences in the averages (Table 2).

In the total sample, Factor 3, Leadership, has the highest average, and Ethics has the lowest.

Regarding standard deviation, Ethics has the highest, indicating greater variability in responses, while Management has the lowest, suggesting more consistency in how participants perceive the factor.

Overall, the responses tend to show moderate variability with significantly high standard deviations, but the different hospital administrations do not show substantial discrepancies among themselves, as detailed in Table 2.

Table 2. Difference between hospitals in the factors of I-NPCS-SF.

	Factor 1 (Management)	Factor 2 (Acts)	Factor 3 (Leadership)	Factor 4 (Ethics)
	Mean±SD			
HF1	78,61±11,19	85,53±11,14	85,09±11,95	75,52±14,14
HF2	79,80±11,13	83,90±11,98	86,00±10,27	77,30±14,73
TS	79,09±11,15	84,87±11,48	85,46±11,28	76,24±14,36

Legend: **HF1**: Private Hospital Facility; **HF2**: Public Hospital Facility; **TS**: Total Sample

The analysis of means and standard deviations revealed significant differences among the various participant categories (Table 3).

Regarding Factor 1, Management, nurses from the Diagnostic Area reported the lowest score (MD 66.40) but also the highest dispersion in responses (SD 22.56), indicating that opinions on this factor vary greatly within the group. In contrast, professional with a Postgraduate Diploma perceived management particularly positively (MD 84.82).

For Factor 2, Acts, the Diagnostic Area again had the lowest score (MD 69.44), while professionals with a freelance contract had the highest (MD 89.94). Part-time workers showed considerable variability in responses for this factor (SD 24.59).

Professionals with a Master's degree demonstrated a highly positive perception of their Leadership (MD 88.69). The lowest mean, once again, was reported by the Diagnostic Area (MD 68.75). The highest variability for Factor 3 was found among part-time workers (SD 24.38).

For Factor 4, Ethics, those with a Master's degree reported the highest score (MD 89.28). In contrast, individuals with less than one year of work

experience perceived their ethical competence as lower (MD 60.26). The Rehabilitation Area showed the greatest judgment dispersion for this factor, with a SD of 20.01.

The statistical analysis then compared the mean competency scores across different operational units using Welch's one-way ANOVA. The results did not show significant differences between the operational units in the overall competency scores.

However, Tukey's tests revealed some differences between specific operational units. In particular, within nursing care management (Management), a significant difference emerged between the diagnostic area and the surgical area ($p = 0.004$), as well as between the critical area and the surgical area ($p = 0.007$). Regarding Leadership, a significant difference was observed between the diagnostic area and the surgical area ($p < 0.001$), suggesting a lower perception of management competencies among professionals in the diagnostic area.

To better understand the influence of variables such as operational unit and work experience on competencies, a linear regression analysis was conducted. The results indicated that the diagnostic and rehabilitation areas had significantly lower scores in Management compared to the surgical area, with estimates of -0.683 ($p = 0.020$) and -0.564 ($p = 0.042$), respectively (Figure 1).

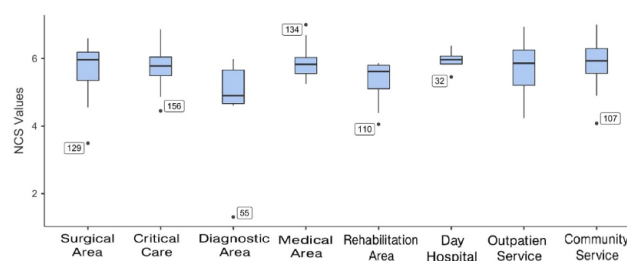


Figure 1. Linear regression analysis of Management competence scores by operational unit.

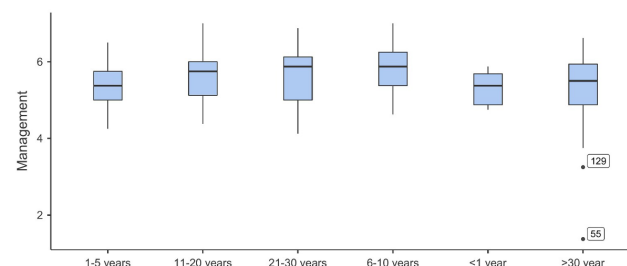


Figure 2. Linear regression analysis of Management competence scores by years of work experience.

Table 3. Mean and Standard Deviation represented by Operational Unit, Gender, Age Group, Educational Qualification, Work Experience, Contract Type, Employment Profile, Work Schedule.

		Factor 1 (Management)	Factor 2 (Acts)	Factor 3 (Leadership)	Factor 4 (Ethics)
		Mean±SD			
Operating Unit	Surgical Area	79,84±10,92	84,58±10,64	86,64±10,23	76,91±12,94
	Critical Area	78,16±8,99	86,42±9,20	86,07±9,09	75,80±13,64
	Diagnostic Area	66,40±22,56	69,44±23,18	68,75±24,98	61,60±15,24
	Medical Area	80,94± 8,21	86,87± 6,59	87,72±6,58	79,67±13,23
	Rehab Area	74,10±6,22	79,36±19,21	79,46±9,77	66,51±20,01
	Day Hospital	83,25±5,66	89,28±4,17	86,30±11,06	80,35±6,83
	Outpatient Services	79,16±11,53	86,01±10,10	85,26±12,27	77,21±15,04
	Territorial Services	82,62±11,37	85,65±10,45	88,00±8,81	78,84±13,69
Gender	Female	79,42±9,99	85,13±9,25	85,63±9,87	75,11±13,86
	Male	79,72±10,20	85,99±12,74	86,90±9,61	81,51±14,05
	Not Declared	16,07	14,28	14,28	39,28
Age Range	20-30 years	78,37±8,34	85,88±7,96	87,01±8,37	72,92±13,23
	31-40 years	81,97±9,36	87,00±7,62	84,94±10,24	78,76±13,8
	41-50 years	81,14±11,19	86,14±10,33	86,86±11,08	81,49±13,1
	>50 years	75,37±15,13	79,98±17,74	82,34±15,42	73,9±16,26
Education Level	Nursing Diploma	73,39±14,83	78,86±17,66	81,7±15,97	71,73±15,98
	Bachelor's Degree in Nursing	79,04±9,46	85,56±8,74	85,93±10,11	74,09±14,35
	Postgraduate Certificate	83,11±9,14	88,54±7,93	87,31±8,47	81,83±11,21
	Master's in Nursing Sciences	82,36±4,96	84,12±2,24	88,69±7,62	89,28±7,14
	Postgraduate Diploma	84,82	77,77	83,33	85,71
Work Experience	<1 year	77,67±6,31	82,34±6,81	87,2±5,53	60,26±13,69
	1-5 years	76,88±8,82	84,08±8,04	85,58±10,3	72,58±13,93
	6-10 years	82,51±9,25	90,06±6,73	88,17±8,34	80,64±10,00
	11-20 years	81,52±10,51	84,31±12,85	86,00±9,64	79,43±14,69
	21-30 years	81,35±10,00	85,84±9,67	85,71±10,71	80,28±14,54
	>30 years	73,57±15,94	80,54±17,65	80,77±17,16	73,28±14,67
Contract Type	Employee	79,13±11,24	84,67±11,61	85,42±11,41	76,26±14,29
	Freelancer	78,27±9,42	89,94±5,64	86,5±7,62	75,59±17,55
Contract Profile	Full-time	79,32±10,06	85,20±10,12	85,98±9,78	76,37±14,09
	Part-Time	75,62±22,58	79,84±24,59	77,61±24,38	74,28±18,73
Work Schedule	Day Worker	81,25±12,75	84,98±12,51	86,04±13,65	78,35±14,45
	Shift Worker	77,64±9,73	84,80±10,79	85,06±9,41	74,81±14,20

Discussion

The definition and evaluation of nursing competencies represent a crucial challenge for defining professional standards, ensuring the quality of care, and ensuring the sustainability of healthcare systems, thus creating the conditions to attract and retain nurses in healthcare (Scavone et al., 2014).

This study aims to investigate self-reported professional competencies of nurses using the I-NPCS-SF tool.

The results of this cross-sectional study showed high mean scores across all factors regarding the self-assessment of nurses' competencies. This is consistent with the findings of Nilsson et al. (2018)Formatting..., who found a high level of self-reported competence among Swedish nurses.

The second-level statistical analysis revealed that advanced education (Master's degrees and Postgraduate Diploma) seems to be associated with higher and more consistent scores across all factors, particularly Leadership and Ethics. This result aligns with the findings of Prendi, which highlighted how higher education correlates with greater professional competence in nurses (Prendi et al., 2022).

Regarding the work environment, the Diagnostic Area presented lower average scores, especially for Management, Acts, and Leadership, suggesting a less positive perception of competencies or possible issues. Professionals with less than one year of experience had a significantly lower evaluation of the Ethics factor, highlighting a potential need for training and support in this area, probably due to less familiarity with ethical issues in the work context. Moreover, work experience seems to play a key role in the development of management competencies.

This result supports the competency development model proposed by Benner's framework (Benner, 2003).

Freelance professionals reported very high scores for Acts, indicating a greater sense of autonomy and professional satisfaction compared to employees.

The Diagnostic Area and part-time workers showed greater variability in responses, indicating that the interpretation of factors may depend greatly on the specific work context.

The surgical and critical areas suggested higher average self-assessment scores of competencies.

The variability related to the work context and contractual profile has not been widely addressed in similar studies (Chae & Park, 2018; Nilsson et al., 2018; Notarnicola et al., 2018; Prendi et al., 2022), representing an interesting area for future research.

This suggests the need for further studies to understand how different work environments influence the perception of nursing competencies.

Implications for practice

This study underscores the need for further research in Italy, involving a broader sample from various regions beyond the North. Repeated use of the I-NPCS-SF can support clinical, educational, and research efforts by identifying

training needs, improving education, and enhancing nurses' satisfaction—key to retention and quality care.

The tool may also help explore links between competencies and critical thinking, clinical reasoning, decision-making, and nursing-sensitive outcomes. However, its use among nurses in managerial or research roles is underexplored, highlighting the need for validation in these contexts.

Finally, it is essential to develop competencies in digital skills, methodological analysis, and emerging roles, especially with the introduction of nurse assistants and advanced clinical training in Italy. Recognizing and measuring these skills is vital for guiding care pathways aligned with the system's evolving demands.

Limitations

The results of this observational study should be interpreted with caution, as there are some limitations.

The convenience sample is limited, making it impossible to generalize the findings of this study. Additionally, the study included hospital settings with different characteristics and only two facilities from the province of Bergamo.

The study was based on nurses' self-assessment of their competencies, a method that may have influenced the results due to its self-referential nature and subjectivity, potentially leading to an overestimation of one's own competencies (Kajander-Unkuri et al., 2014; Lakanmaa et al., 2014).

Conclusions

The present study contributes to bridging the existing knowledge gap in the Italian context, where research on nursing competence remains limited.

Alongside future investigations, it supports a deeper understanding of nursing skills in Italy, representing a crucial step towards enhancing the quality of nursing care and informing future research and targeted educational strategies.

By providing valuable insights into the investigated settings, the study offers practical implications for improving staff organization and management, considering the differences observed among the analyzed groups. It highlights the importance of strengthening training in ethics and management, particularly

for less experienced professionals; addressing the challenges perceived in the Diagnostic Area to understand the reasons behind lower scores; and evaluating the support mechanisms for part-time workers, whose responses demonstrated notable variability (Osingada et al., 2015).

In conclusion, systematically assessing competencies, identifying training needs, addressing gaps through targeted education, and enhancing nurses' satisfaction with their own skills may play a pivotal role in retaining nursing staff within the healthcare system and ensuring safe, high-quality patient care.

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