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Design and implementation of a semi-quantitative tool for alarm management system assessment in Neonatal Intensive Care Unit

TESI DI LAUREA MAGISTRALE IN
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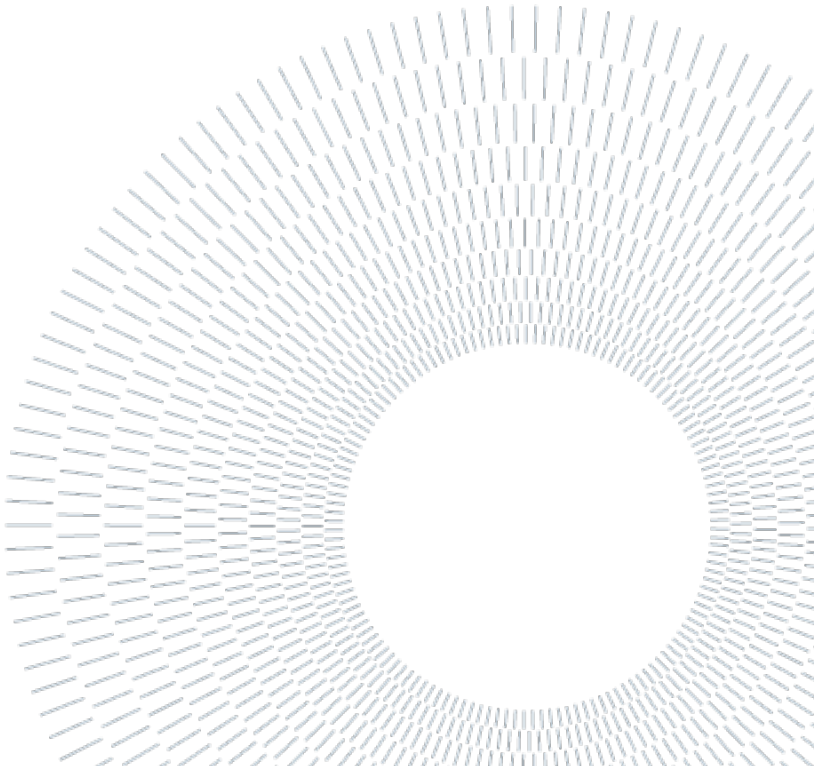
A chi ricorda che il progresso delle
tecnologie medicali trova il suo valore più alto
nella capacità di assistere e proteggere la vita più fragile.



Abstract

As part of the New Building project of the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, a reorganization of the Neonatal Intensive Care Unit (NICU) is currently underway. This reorganization aims not only to redesign the spatial layout but also to enhance the quality of care by reducing the risk of cross-infections and noise pollution. To support this transformation, which includes the introduction of a distributed alarm management system and Silent Rooms, a pilot study has been designed to be implemented within the current NICU. The study is structured in two phases: during the "pre" phase, the staff operates with the existing centralized alarm system, while in the "post" phase, the new distributed model will be introduced. This work focuses on the development of a semi-quantitative assessment tool, based on a Systematic Literature Review, and on its first application during the "pre" phase of the pilot project. The analysis of the collected data, through clustering and statistical methods, enabled the identification and characterization of distinct user groups, represented as Personas defined by specific behavioral and perceptual patterns. These exhibited critical issues consistent with those reported in the literature for open-bay models, particularly concerning acoustic load and the timeliness of correspondence between alarm and patient. In addition to these shared user challenges, significant differences were observed between the two archetypes regarding the perceived completeness of information for decision-making in alarm situations, the level of confidence with technology, and the degree of disruption to workflow continuity caused by frequent alarm interruptions. The results obtained allow the definition of a baseline describing the behaviors and needs of the archetypes of users of the centralized system. Comparing these results with those emerging from the "post" phase will make it possible to evaluate the actual impact of the new monitoring system, identifying improvements as well as potential new criticalities to be addressed before the transition to the New Building. In this way, the move to the new NICU can take place safely and with full awareness, further enhancing the high standards of safety and effectiveness in neonatal care that already characterize the Clinica Mangiagalli.

Keywords: Neonatal intensive care unit, alarm management system, semi-quantitative questionnaire, systematic review, user persona.

Abstract in italiano

Nell'ambito del Nuovo Building della Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, è in corso una riorganizzazione della Terapia Intensiva Neonatale (TIN), che mira non solo a ridefinire gli spazi, ma soprattutto a migliorare la qualità dell'assistenza, riducendo il rischio di infezioni crociate e l'inquinamento acustico. A supporto di questa trasformazione, che prevede l'introduzione di un sistema di gestione degli allarmi distribuito e di Silent Room, è stato progettato uno studio pilota da implementare nei locali dell'attuale TIN, articolato in due fasi: nella fase "pre" il personale opera con l'attuale sistema di allarmi centralizzato, mentre nella fase "post" è prevista l'introduzione del nuovo modello distribuito. Il presente lavoro si concentra sullo sviluppo di un tool di valutazione semi-quantitativo, basato su una Systematic Literature Review, e sulla sua prima applicazione nella fase "pre" del progetto pilota. L'analisi dei dati raccolti, condotta attraverso metodi di clustering e analisi statistica, ha permesso di identificare e caratterizzare distinti gruppi di utenti, rappresentati come Personas definite da specifici pattern comportamentali e percettivi. Queste hanno evidenziato criticità coerenti con quanto riportato in letteratura per i modelli open-bay, in particolare riguardo al carico acustico e alla tempestività di corrispondenza tra allarme e paziente. Oltre a queste difficoltà comuni agli utenti, sono emerse differenze significative tra i due archetipi individuati, relative alla percezione della completezza delle informazioni utili al decision-making in situazioni di allarme, al livello di confidenza con la tecnologia e al grado di interruzione della continuità operativa causata dalle frequenti segnalazioni di allarme. I risultati ottenuti permettono di definire una baseline che descrive i comportamenti e le necessità degli archetipi di utilizzatore del sistema centralizzato. Il confronto di tali risultati con quelli che emergeranno dalla fase "post" consentirà di valutare l'impatto effettivo del cambiamento del sistema di monitoraggio, individuando le migliorie apportate e, soprattutto, eventuali nuove criticità da affrontare prima del trasferimento nel Nuovo Building. In questo modo, il passaggio alla nuova TIN potrà avvenire in modo sicuro e informato, migliorando ulteriormente i livelli di sicurezza ed efficacia delle cure neonatali che già contraddistinguono la Clinica Mangiagalli.

Parole chiave: Terapia intensiva neonatale, sistema gestione allarmi, questionario semi-quantitativo, revisione sistematica, user persona.

Contents

Introduction

In recent years, the healthcare system in the Lombardy region has undergone profound changes, shaped by the growing complexity of patient needs, increasing organizational demands, and the rapid pace of technological progress. Within this framework, the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, one of the most historically significant and scientifically advanced healthcare institutions in Italy, has launched an ambitious redevelopment plan through the construction of the new Padiglione Sforza. Rather than a simple infrastructural intervention, this project marks a milestone in structural, organizational, and technological renewal, seeking to transform care delivery by combining advanced technologies, patient-centred principles, and innovative clinical workflows. Among the specialities involved in this transition, the Neonatology and Neonatal Intensive Care Unit (NICU) assumes relevance. As a regional and national reference centre, the NICU of the Policlinico manages high patient volumes and complex cases, including extremely preterm infants and critically ill newborns. Within this high-risk environment, the reposition to the new building cannot be regarded simply as the transfer of neonatal cots to a different space, but rather as a systemic transformation that redefines care delivery, encompasses advanced technologies, and reshapes organizational models to guarantee the highest standards of care. At the core of this transformation is the redesign of alarm management. In the traditional open bay configuration of the NICU, alarms generated by multiparameter monitors and life-support devices were transmitted locally at the bedside through acoustic and visual signals. While this approach ensured immediate perception, it also created several well-known problems. A large proportion of alarms are clinically irrelevant or artefactual, producing a constant flow of signals that contributes to alarm fatigue. This condition is marked by cognitive overload, a reduced ability to distinguish between relevant and irrelevant events, and an increased risk of delayed or missed responses to critical situations. In an environment where seconds can determine outcomes, this represents a serious threat to patient safety. At the same time, the continuous acoustic burden has negative effects on neonatal stability, since clinical outcomes are closely related to reduced environmental stress. The new system, which organizes the NICU into

sectors and groups, is based on a distributed architecture that fundamentally changes the way alarms are generated, transmitted, and managed. Rather than being transmitted as audible signals throughout the unit, alarms are routed to a central server and displayed at the monitoring station of the sector to which the beds belong. At the same time, alarms are forwarded to the mobile device of the operator responsible for that specific group of patients, within a configuration reinforced by structured delegation and escalation protocols that reduce the risk of delay or loss. The expected impact of this innovation is broad. Clinically, it is expected to reduce non-significant alarms, improve the reliability of alarm recognition, and ensure timelier responses, with direct benefits for patient safety and outcomes. Due to the decrease in noise pollution, the system also establishes a calmer environment that promotes neonatal stability, rest, and recovery, while providing a more comforting experience for families. Financially, a decrease in negative incidents and shorter periods of NICU hospitalization are expected to lead to considerable cost savings. By reducing the number of alarms, healthcare operations can utilize nursing resources more effectively, which helps to lessen stress and enhance both staff satisfaction and productivity. Although the transition promises substantial benefits, its implementation requires overcoming significant challenges. The magnitude and complexity of these changes make a structured pilot study essential. For this reason, the pilot study is conducted in the less critical areas of the current NICU, which is divided into three zones with different levels of care, thus providing a suitable context for experimentation. The pilot allows the system to be tested under real conditions, its technical performance to be measured, and staff behaviour to be observed in practice. The data collected include both quantitative indicators and qualitative feedback on usability, cognitive load, and overall staff satisfaction. This integrated approach makes it possible to identify strengths and weaknesses in advance, ensuring that corrective measures are introduced before the full-scale migration to the new facility. Within this context, the present thesis is situated. Its aim is not limited to reporting the outcomes of the pilot study, but extends to the design of a structured, evidence-based framework for the assessment of the new alarm management system. The objectives of the thesis are to define domains of investigation that capture both technological and organizational implications, to design and apply data collection tools tailored to this context, and to establish analytical methods that transform raw data into evidence capable of informing clinical, strategic, and operational decisions. The distinctiveness of this work lies in the evaluation of a complex socio-technical system based on real evidence rather than assumptions. By combining quantitative

measurement with qualitative analysis, the thesis seeks to offer a comprehensive assessment of the pilot and a replicable framework for evaluating similar processes of technological and organizational innovation in intensive care units. In doing so, it aims to contribute to a safer and more effective transition to the new NICU, as well as to provide broader insights into advanced alarm management systems in neonatal intensive care.

Chapter 1 | Context

1.1. Institutional framework

Within the Lombardy healthcare system, the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, commonly referred to as Policlinico di Milano, has emerged as one of the most significant institutions in the healthcare sector since its foundation in April 1456. Healthcare is provided across the entire life cycle, from preconception to adulthood, thanks to a team of qualified professionals and state-of-the-art facilities. Its healthcare services go beyond the local dimension, as they are fully embedded in national and international networks for both care and scientific collaboration [1][2]. Among its areas of excellence, particular relevance is given to women's health and maternity care, managed in the Clinica Mangiagalli, which records over 6,000 births annually and hosts the most active obstetric-gynecologic emergency department in Lombardy. The clinic is also involved in advanced research in the fields of assisted reproduction and fetal surgery and is acknowledged for its excellence in the management of endometriosis [3]. The hospital is a national leader in organ transplantation, particularly liver, lung, and kidney transplants. It hosts the North Italy Transplant program (NITp) and the Regional Transplant Coordination Center, managing procedures for over 20 million citizens. Since 1972, more than 37,000 organ transplants have been performed, with post-transplant success rate at one year above 90% [4]. The treatment of rare diseases is another central area, with over 13,000 registered cases and more than 300 conditions managed, making the hospital a reference point not only for Lombardy but for the entire country. The Policlinico also plays a major role in hematology and blood coagulation disorders, with nationally recognized programs for hemophilia, thrombosis, and other coagulopathies [5]. In the field of hepatology, the hospital is acknowledged for its work on antiviral therapy for hepatitis B and C, liver cancer, and portal hypertension. In addition, the Policlinico is involved in epidemiological and occupational medicine research, especially on the prevention of mesothelioma and the health impact of air pollution. Emergency departments, including general, pediatric, obstetric-gynecologic, record over 100,000 visits annually and serve as a regional benchmark for urgent care. Another area of excellence is intensive care and emergency medicine. The hospital is a pioneer in the use of ECMO (Extra Corporeal

Membrane Oxygenation), a heart-lung support technique for critically ill patients [6]. The hospital's scientific activity ranks first among Italian IRCCS (Scientific Institutes for Research, Hospitalization and Healthcare) for both the quality and quantity of its scientific publications. Featuring more than 50 certified research centers and a clinical operations framework that meets top global standards, the Policlinico conducts a large range of both interventional and non-interventional studies. These studies collectively contribute to translational biomedical research, which is research performed directly on patients, applying scientific findings in clinical settings. This strong connection between research and patient care allows for the creation, evaluation, and application of new treatments and technologies, positioning the institution as an international leader in medical innovation [7]. Daily clinical practice benefits from investment in advanced technologies, such as robotic surgery, fluorescence-guided surgery, and minimally invasive laparoscopic techniques. Teams regularly employ 4K endoscopes, ultrasound dissectors, and high-resolution imaging, including prenatal neuroimaging starting from the 19th week of gestation. The hospital is also a hub for the collection, conservation, and dissemination of biological materials. It hosts the Milan Cord Blood Bank with over 9,000 stored donations used in more than 500 stem cell transplants in Italy and abroad. Additional infrastructures include a Biobank with about 200,000 cryopreserved samples (serum, cells, DNA, RNA), the Rare Blood Bank, the Human Milk Bank, a Semen Cryobank and a Tissue Bank. Finally, the “Franco Calori” Cell Factory, with GMP-certified facilities, enhances the production of advanced cell therapy products and supports stem cell research.

1.1.1. The Padiglione Sforza

The Policlinico has traditionally utilized a pavilion-based structure, with facilities arranged according to specific medical specialties. Although this structure was previously effective, it now leads to disjointed patient journeys and complicated internal and external processes. Currently, the model is viewed as outdated, since integrated and patient-focused designs are favored to enhance efficiency and quality of care provided. For these reasons, today, the Policlinico is undergoing one of the most significant transformations in its history. A strategic turning point occurred in 2014 with the establishment of the Fondo Ca’ Granda, a closed-end fund managed by Investire SGR, created to finance the redevelopment of the hospital’s infrastructure. Although the project also drew on other resources, the fund, based on principles of social housing, served as the primary one, generating revenues

distributed between property sales (43%) and rentals (57%). Thanks to this model it is possible to address significant investment with minimal reliance on public funds [8]. The core of this redevelopment is the creation of the Padiglione Sforza, a technologically advanced pavilion designed to centralize acute care services in a single structure. The project aims in modernize existing infrastructure, improve functional efficiency, and align the hospital's physical and organizational configuration with emerging healthcare needs. These include the growing demand for personalized, high-tech medical services, the challenges posed by an aging population and the consequently increasing burden of chronic conditions. The Padiglione Sforza will serve as the functional and symbolic centerpiece of the new hospital. It is designed to house over 800 inpatient beds and accommodate key clinical departments, including two specialized emergency services (pediatrics and obstetrics-gynecology), surgical theaters, intensive care units, and advanced diagnostic imaging facilities. The surrounding historical pavilions will be renovated and repurposed for outpatient services, day hospitals, administrative offices, and research activities, thus enabling a clear and effective separation between inpatient and outpatient care pathways. Architecturally, the new Pavilion consists of two main towers, the North and South Blocks, each rising seven stories above ground and includes two underground levels, and a central podium, known as the Central Plate. Above this structure is a 7,000 m² therapeutic garden, designed as a multifunctional outdoor space that supports patient recovery, staff wellbeing, and therapeutic activities. The Central Plate contains core medical facilities as reported in Table 1.1.

Table 1.1: Functional layout of facilities and services by floor level and type within the Central Plate.

<table>
<tr><th colspan="3">Central Plate</th></tr>
<tr><td rowspan="3">3</td><td colspan="2">Air treatment unit
Non-denominational worship area
Administrative areas</td></tr>
<tr><td>Ordinary ward</td><td rowspan="2">Neonatologia e terapia intensiva neonatale</td></tr>
<tr><td>Nursery</td></tr>
<tr><td>2</td><td colspan="2">Operating block 2
Maternity ward</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">Operating block 1</td></tr>
<tr><td>Hemodynamics and electrophysiology</td><td>Cardiologia</td></tr>
</table>

	Interventional radiology	Radiologia
	Operating block 3	
0	Commercial gallery and pedestrian passage Auditorium	
-1	Sterilization center Hospital canteen and kitchen Staff changing rooms	
-2	Storage and logistics hub	

Functionally, the North Block will house departments focused on adult care, including diagnostic imaging (X-ray, ultrasound, CT, MRI), dialysis (both adult and pediatric), cardio-surgical intensive care, coronary units, general intensive care, semi-intensive and standard inpatient wards, as detailed in Table 1.2.

Table 1.2: Functional layout of facilities and services by floor level and type within the North Block.

North Block		
6	Ordinary ward	Ematologia Oncologia medica Cardiologia
	Semi-Intensive Care Unit	Ematologia
5	Ordinary ward	Medicina - Alta intensità di cura Pneumologia e fibrosi cistica Geriatria Medicina del lavoro
	Semi-Intensive Care Unit	Medicina - Alta intensità di cura Pneumologia e fibrosi cistica
4	Ordinary ward	Malattie Infettive Medicina - Emostasi e trombosi Medicina a indirizzo metabolico
3	Ordinary ward	Gastroenterologia ed epatologia Gastroenterologia ed endoscopia Medicina - Immunologia e allergologia Nefrologia, dialisi e trapianti di rene

		Urologia Chirurgia generale - Trapianti di rene
2	Ordinary ward	Otorinolaringoiatria e chirurgia cervico facciale Oculistica Chirurgia maxillo-facciale e odontostomatologia Ostetricia (Patologia della gravidanza)
1	Intensive Care Unit	Anestesia e terapia intensiva adulti (Rianimazione cardiochirurgica, Rianimazione generale)
	Semi-Intensive Care Unit	Cardiologia
0	Dialysis	Nefrologia, dialisi e trapianti di rene Nefrologia e dialisi pediatrica – Trapianti di rene
-1	Imaging	Radiologia
-2	Storage and logistics hub	

The South Block will focus on maternal and pediatric care, housing emergency departments, neonatal and pediatric intensive care units, neonatology services, and private patient accommodations, as outlined in Table 1.3.

Table 1.3: Functional layout of facilities and services by floor level and type within the South Block

South Block		
6	Ordinary ward	Ginecologia Solvenza “Santa Caterina” Neonatologia e terapia intensiva neonatale
5	Ordinary ward	Chirurgia pediatrica Urologia pediatrica Nefrologia e dialisi pediatrica - Trapianti di rene Pediatria - Gastroenterologia, epatologia, trapianto pediatrico e fibrosi cistica
4	Ordinary ward	Pediatria - Pneumoinfettivologia Pediatria - Immunoreumatologia Pediatria - Gastroenterologia, epatologia, trapianto pediatrico e fibrosi cistica
3	Ordinary ward	Ostetricia Neonatologia e terapia intensiva neonatale

2	Intensive Care Unit	Neonatologia e terapia intensiva neonatale
	Semi-Intensive Care Unit	
	Ordinary ward	
1	Ordinary ward	Cardiochirurgia Chirurgia vascolare Chirurgia toracica e trapianti di polmone Chirurgia generale - trapianti di fegato Chirurgia generale e mini-invasiva
0	Imaging diagnostics	Radiologia
	Intensive Care Unit	Anestesia e terapia intensiva donna-bambino
	Emergency room	Pronto soccorso accettazione ostetrico ginecologica e PMA Pronto Soccorso Pediatrico
-1	Hospital pharmacy	
-2	Storage and logistics	

The two basement levels contain essential logistical and technical services. Internal connections are ensured by pedestrian paths, underground tunnels, and a covered aerial bridge, maintaining uninterrupted integration between the new and existing structures. The design adheres strictly to environmental sustainability principles. High-efficiency MEP (mechanical, electrical, plumbing) systems are supported by automated energy management platforms. Heating and cooling are provided by systems powered through diversified, renewable energy sources. Rainwater harvesting and LED-based lighting throughout the facility further reduce energy consumption and environmental impact. Interior lighting systems incorporate biodynamic technology that simulates the circadian rhythm, thus supporting patient recovery and enhancing overall comfort [2][9].

1.2. Organizational standards for the maternal and neonatal care network

Historically, healthcare systems have tended to fragment the care pathway, treating pregnancy, childbirth, and the postpartum period as distinct phases. This compartmentalization has frequently led to inefficiencies and clinical errors, undermining the continuity and effectiveness of care. The understanding of the mother-newborn dyad as a single psycho-biological unit is relatively recent but increasingly recognized in both clinical and organizational contexts. To effectively support this unified biological and care process, the healthcare system must offer a continuous and coordinated care pathway, spanning from community-based prenatal services to labour wards and neonatal intensive care units. Within this framework, maternal and neonatal care, one of the most sensitive and complex areas of public health, must be treated as a single, integrated field. Its effectiveness requires collaboration across different care settings and professional domains, with the shared goal of delivering high standards of quality, safety, and resource efficiency. In this context, the Hub & Spoke model has proven particularly effective. It supports a territorial distribution of services, that ensures local accessibility for early identification of maternal or neonatal risks and the centralization of complex cases in specialized centres equipped with advanced technologies and expert clinical teams [10]. In this regard, a key challenge lies in maintaining a balance between the centralization of expertise and the need to ensure territorial accessibility. This balance remains crucial even in the current context of declining birth rates, where every organizational decision must aim to preserve the highest possible standards of quality and patient safety. The system is structured into two main levels of care:

1. First-level centers: manage physiological pregnancies and low-risk obstetric cases, as well as mild to moderate maternal or neonatal conditions.
2. Second-level centers: in addition to providing first-level care, are equipped to handle high-risk pregnancies and severe maternal-fetal or neonatal pathologies [1][11].

[1]To ensure an appropriate level of care and the correct allocation of resources, it is important to distinguish two levels of care within Neonatal Pathology (Ministry Code 62). This distinction reflects the significant differences in clinical needs, care intensity, and length of hospital stay between neonates admitted to Neonatal Pathology units in first-level birth centers, and those transferred from a Neonatal Intensive Care Unit (NICU) and currently hospitalized in second-level birth centers. Therefore, the following nomenclature is proposed:

1.2.1. First-level centers

First-level birth centers represent the foundational level in the maternal and neonatal care network. Their activity is oriented toward the management of low-risk pregnancies and newborns with physiological or mild to moderate conditions. Despite these centers may vary significantly in terms of annual delivery volumes, national and international evidence has led to the definition of reference thresholds. Ideally, a first-level center should manage more than 1,000 births per year, as this number supports clinical competence and maintains high standards of quality and safety. However, a minimum threshold of 500 births per year is considered acceptable, particularly in areas where geography and population density create logistical challenges. Anyway, it is important to highlight that the amount of cases does not necessarily reflect safety or quality. Centers should be assessed based on their organizational structures, the presence of qualified personnel and facilities, as well as their historical clinical outcomes. To provide care that is specific, continuous, and safe, first-level centers must include:

1. A Neonatology Unit (Rooming-In/Nursery) for healthy newborns.
2. A Neonatal Pathology Unit to manage intermediate-risk conditions, where sufficient staff, resources, and structural capacity are available.

In exceptional cases, a first-level birth center may operate with fewer than 500 births per year, but only in areas with severe geographical challenges, where long travel distances and times to alternative facilities could compromise access to care. Anyway, even in such exceptional cases, the center must meet all the structural, technological, clinical, and organizational requirements expected of a first-level facility. Given the lower volume and thus reduced clinical exposure of healthcare professionals in these centers, it is essential to implement targeted training programs, which should include either annual training periods at second-level birth centers or rotation of clinical staff from close high-volume centers (either second-level or first-level with ≥ 1,000 births/year) [13]. Having outlined the general framework, the description of first-level birth centers can be further elaborated through thematic as target population, organizational standards and services

1. First-level birth center: Nursery (Ministry Code 31) + Neonatal Pathology (Ministry Code 62 with the addition of sub-code 02)
2. Second-level birth center: Nursery (Ministry Code 31) + Neonatal Pathology (Code 6202) + Sub-Intensive Neonatal Care (Ministry Code 62 with the addition of sub-code 01) + NICU (Ministry Code 73) [12]

offered, structural and technological standards, and professional skills and training. The following discussion details the target population and the structural and technological standards.

1.2.1.1. Target population

As previously said, neonatal care in first-level birth centers is generally reserved for newborns who meet specific eligibility criteria. When the facility manages between 500 and 999 births per year, care is typically provided to neonates with a gestational age of at least 36 weeks and a birth weight equal to or greater than 1,900 grams. In centers with an annual volume of 1,000 or more births, the inclusion criteria expand to include newborns with a gestational age of 34 weeks or more, a minimum weight of 1,750 grams, and a birth weight appropriate for gestational age, defined as falling between the 10th and 90th percentiles. The continuation of care within this level facility is considered appropriate only when certain clinical conditions are clearly met. These include evidence of good neonatal adaptation, demonstrated by an Apgar score of at least 7 at 5' and umbilical cord blood gas values that are either within the normal range or characterized by a pH above 7.0 and a BE greater than –12; neurological assessment using the Sarnat score conducted every 60 minutes; respiratory stability must also be confirmed, particularly if oxygen supplementation is needed for less than 12 hours and the required fraction of inspired oxygen (FiO_2) does not exceed 40%. Additionally, the presence of jaundice must not be linked to alloimmunization and should show a favorable response to standard phototherapy; hypoglycemic episodes, if present, must resolve promptly with oral, enteral, or intravenous treatment using peripheral access and standard therapeutic regimens; the patient does not present any congenital anomaly or malformation that requires urgent diagnostic investigation or higher-level care. Finally, in cases where a non-cyanotic congenital heart defect is suspected, care may continue at the first-level center only if a timely echocardiographic evaluation can be performed by a neonatologist or another healthcare professional with certified expertise in neonatal cardiology. If any of these conditions is not met, it is necessary to activate the Neonatal Emergency Transport System (STEN) and arrange for immediate transfer of the newborn to a second-level referral center equipped to provide the required level of intensive and specialized care [13].

1.2.1.2. Structural and technological standards

The structural and technological standards applied in neonatal care environments consider both European (EFCNI) and American (AAP) benchmarks. The areas of rooming-in, neonatal resuscitation, and neonatal pathology are each characterized by specific needs in terms of space and technological infrastructure [14].

Rooming-in

In rooming-in settings, where mothers and newborns stay together post-delivery, structural provisions must reflect standard hospital room dimensions and technologies. For a birth center with approximately 1,000 births per year, it is necessary to ensure the availability of up to 18 or 19 cots to cover an average occupancy rate of 75%. It is strongly recommended that rooms are designed to host two mothers and their respective newborns, each room equipped with its own bathroom. When planning new constructions or renovations, rooms with a maximum of two beds and attached sanitary facilities are considered optimal. From a technological standpoint, rooming-in units typically do not require high-tech equipment. However, they must guarantee the availability of essential tools such as incubators or heated cribs, breast pumps, devices for phototherapy in cases of neonatal jaundice, pulse oximeters, and point-of-care testing for blood glucose and bilirubin levels. Access to a blood gas analyzer using micro-methods must also be ensured.

Neonatal Resuscitation Area (Isola Neonatale)

The isola neonatale is a critical component of both delivery rooms and Labour, Delivery, and Recovery (LDR) rooms[2]. Structurally, each delivery or LDR room must be equipped with either an independent room of at least 15 square meters or a designated area of no less than 4 square meters. The setup must allow for the

[2]Definitions:
Delivery rooms represent a more traditional model of maternity care, designed to accommodate only the final phase of childbirth, the delivery phase. In this approach, the mother must be transferred between separate units for labor, delivery, and postpartum recovery.
LDR rooms, also known as Single-Room Maternity Care (SRMC), represent a more integrated approach, where the woman remains in the same environment throughout the entire process, from labor to delivery to immediate postpartum recovery. This model minimizes care fragmentation and increases patient satisfaction [15].
Operating rooms for delivery represent dedicated space designed for elective and non-elective cesarean sections. C-sections are surgical procedures in which one or more fetuses, along with the placenta and amniochorionic membranes, are delivered through incisions made in the abdominal wall (laparotomy) and the uterus (hysterotomy) [16].

simultaneous resuscitation of at least two newborns. Similarly, every operating room designated for cesarean deliveries must include neonatal resuscitation area. Each neonatal resuscitation station must be equipped with two oxygen outlets, two medical air outlets, and two vacuum outlets. There must be two gas mixing systems with humidifiers, preferably using two separate blenders, and two pressure-limiting valves for gas delivery. A minimum of six electrical outlets must be available. The station must include a resuscitation bed equipped with a radiant heater, servo-controlled temperature system, three-sided access, and a non-compressible mattress. Ventilation devices, such as a bag valve mask and T-piece, must be present, together with a laryngoscope and, if the staff is trained, a laryngeal mask. Additionally, sets of consumables are required for manual ventilation and intubation, umbilical vessel cannulation, and thoracic drainage procedures. Further technological provisions include a watch, two volumetric pumps, two percutaneous pulse oximeters, and a multiparameter monitor capable of arterial pressure measurement. There must also be an incubator or infant warmer, a medication and emergency equipment cart, a changing table, and a transport incubator meeting STEN specification. At least one emergency aspirator, powered either electrically or by battery, must be available in the operating and delivery areas. Continuous 24-hour access to a blood gas analyzer with lactate measurement capability must be guaranteed, as must the availability of an ultrasound machine with neonatal probes for emergency use. Alarm systems should be clearly visible and designed for rapid, simultaneous activation of all personnel involved in neonatal resuscitation. Finally, a dedicated telephone line must be available for communication between Hub and Spoke centers.

Neonatal Pathology

The neonatal pathology unit provides intermediate care and must be designed based on the expected hospitalization rate among live births and the average length of stay. The layout should include sufficient space to allow mothers to remain next to their hospitalized newborns.

Each bed in the neonatal pathology unit must be equipped with two oxygen outlets, two medical air outlets, and two vacuum outlets. One gas blender system with a humidifier must be available per bed. There should be four electrical outlets, at least two of which are powered through an inverter system. Each patient station requires a servo-controlled incubator or heated crib. Continuous monitoring of heart rate, respiratory rate, and body temperature must be guaranteed through a multiparameter monitor, ideally with integrated blood pressure measurement and

alarm centralization at the nursing station. Each bed must also be equipped with a pulse oximeter and two infusion pumps, either volumetric or syringe-based, for medication administration.

1.2.2. Second-level centers

Second-level birth centers represent the highest level of care within the maternal and neonatal assistance network, ensuring comprehensive management of pregnancies and births with high levels of complexity and clinical risk. These facilities are designed to care women with pre-existing medical conditions or complications arising during pregnancy through the Maternal-Fetal Medicine (MFM)[3], as well as newborns requiring high-intensity and high-complexity support in Neonatal Intensive Care Units (NICU). To ensure both clinical competence and safety, MFM and NICU centres should provide care for at least 50 Very Low Birth Weight (VLBW) patients per year. For safety reasons, volumes below 25 VLBW infants per year are strongly discouraged. Moreover, the total annual delivery number for facilities hosting a second-level birth centre should exceed 1,500 births to maintain clinical expertise. As with first-level centers, volume alone is not a sufficient indicator of quality or safety. Organizational structure, care protocols, staffing, infrastructure, and historical clinical outcomes must all be considered during service planning and evaluation. Nevertheless, it is recommended that each NICU maintains a minimum of 8 beds, with a strong recommendation not to fall below 4 beds to ensure operational capacity and patient safety. Infants should be assigned to care settings that strictly match their clinical condition, with transfers from NICU to lower-intensity units (e.g., Sub-Intensive Care or Neonatal Pathology Units) as soon as intensive criteria are no longer met [13][17]. Discharges to home generally occur from intermediate care settings, not directly from NICU, therefore

[3]The term Maternal-Fetal Medicine (MFM) refers to the set of activities and functions aimed at the care of complex maternal-fetal conditions, which require a high level of obstetric and gynecological expertise (both knowledge and clinical experience). To achieve the highest level of effectiveness and efficiency through continuity of care, it is essential to ensure organizational and structural contiguity with Neonatal Intensive Care Units, as well as a volume of activity consistent with the high degree of professional experience required. Only through this organizational model is it possible to define the role of Hub within the maternal and child care network and to enable the proper functioning of maternal (STAM) and neonatal (STEN) transport systems. It is strongly recommended that MFM services, along with those for physiological pregnancies or pregnancies with low-to-intermediate risk, fall under a single level of organizational responsibility (possibly at the departmental level in the case of high volumes or specific expertise), to ensure homogeneity and continuity of care.

a discharge rate higher than 5% (excluding deaths and emergency transfers) is considered inappropriate and may indicate systemic inefficiencies. Some second-level centers may also develop highly specialized services, such as fetal surgery, neonatal dialysis, ECMO, pediatric cardiac surgery, or neurosurgery. While these capabilities do not change the center's classification, they designate the facility as a Hub for those specific services within the network.

1.2.2.1. Target population

Second-level neonatal care is designed for all clinical conditions that cannot be safely managed within a first-level birth center. Newborns requiring second-level care include those with gestational age under 34 weeks or weighing less than 1,750 grams at birth. It also includes those in need of oxygen therapy at concentrations higher than 40% for more than 12 hours (conditions that exceed the capacity of first-level centers). For newborns with severe or unstable health issues, particularly those needing respiratory assistance, like nCPAP or intubation, as well as those who have just been taken off ventilation and might still be vulnerable to apnea episodes, admission to NICU is crucial. It also applies to newborns needing central vascular access or undergoing complex procedures like inotrope infusions, administration of vasodilators or prostaglandins, chest drainage, or postoperative monitoring after surgery or tracheostomy. NICU admission is also necessary in cases of urgent surgical needs, serious metabolic disorders that require immediate intervention, parenteral nutrition, repeated seizures, clinically significant apnoea, or therapeutic hypothermia. More broadly, any newborn considered clinically unstable should have access to a NICU. To ensure optimal use of human, structural, and technological resources, NICU admission should be provided exclusively for those newborns who meet criteria previously reported. Once stabilization has been achieved, NICU infants are generally transferred to Sub-Intensive Care or Neonatal Pathology units before discharge, to ensure gradual transition to home care safely [13].

1.2.2.2. Structural and technological standards

About structural and technological standards, rooming-in, isola neonatale, and neonatal pathology features are the same of those of first-level facilities, with some additional specifications primarily concerning isola neonatale and rooming-in. In the former, it is additionally required the simultaneous resuscitation of at least three newborns, rather than two, and a dedicated transport incubator equipped with independent power supply, backup medical gas reserves, and systems for

ventilatory support and monitoring during transfer to the NICU. For rooming-in, continuous monitoring of heart rate, respiratory rate, and body temperature is also required in addition to the baseline standards. In addition to these three areas, the second-level falicities are characterised by sub-intensive care units and NICU.

Sub-Intensive Care Unit

Flexibility in design is important. As an intermediate level of care, sub-intensive units should be able to temporarily support intensive care needs in case of emergencies. Moreover, enough space for mothers to stay close to their newborns, ideally with a comfortable chair next to the crib, is required, to promote bonding and presence during care. Technologically talking, each bed must be equipped with at least two oxygen sources, two medical air outlets, two vacuum points, and a gas blender with humidifier. There must also be six electrical outlets per bed, including at least two connected to an emergency power supply. Access to a servo-controlled incubator or warming crib should be guaranteed to each newborn, along with continuous vital sign monitoring, including heart rate, respiratory rate, and blood pressure. Other key equipment includes a pulse oximeter, at least three infusion pumps, and the ability to carry out urgent ultrasound exams (cranial, cardiac, and abdominal) using neonatal-specific probes.

NICU

The structural and technological standards for NICU are presented with a higher level of detail. This level of specificity, as outlined in Table 1.4 and Table 1.5, is necessary to ensure a proper understanding of the elements discussed in the following sections [18][19][20].

Table 1.4: Structural standards for NICU

Structural standards	
1	It is recommended that the NICU be situated near the delivery room and the operating theatre designated for C-sections, or at minimum, be functionally connected through dedicated pathways.
2	In Hub centers, it is strongly advised to provide immediate access to the hospital's main ambulance entry point, as well as a direct connection to a helicopter landing pad, where such a service is operational.
3	The presence of an entry area equipped with an appropriate filter zone is mandatory prior to entering the unit. Where separate access routes exist, an individual anteroom should be provided for each entrance.

4	A standard NICU module is ideally composed of eight beds, which corresponds to the annual load of approximately 50 VLBW infants. In settings with lower case volumes, smaller modules should be considered. The eight beds do not account for admissions related to post-surgical care and admissions beyond the first month of life.
5	Every open-space care area ought to offer between 11 and 18 square meters for each bed, guaranteeing a minimum space of 2. 5 meters between beds to support effective workflow.
6	It is recommended that at least one single-family room (SFR) be made available for pre-discharge hospitalization, with a surface area of no less than 14 to 18 square meters. In the case of new construction, at least 50% of NICU beds should be designed as SFRs with a minimum surface area of 14 to 18 square meters.
7	It is also advisable to provide, potentially in shared use with the sub-intensive care unit, accommodation for 24-hour parental presence
8	It is recommended that workstations be positioned in direct visual and spatial proximity to neonatal patient areas. These stations should be equipped with centralized monitoring systems for the continuous observation of vital signs and be integrated into the hospital's information network, allowing access to electronic medical records.
9	It is recommended the presence of a dedicated space for basic laboratory diagnostics.
10	If parenteral nutrition (TPN) and intravenous medication bags are not prepared in a centralized pharmacy, a sterile preparation room must be available. This room should include a laminar flow hood and meet all the requirements for aseptic compounding.
11	The provision of isolation negative-pressure rooms is strongly encouraged for the care of neonates infected or colonized with multidrug-resistant organisms or viral pathogens.

Table 1.5: Technological standards for NICU

Technological standards	
1	For each NICU bed, infant warmer and/or incubator with an appropriate radiant surface is required.
2	For each NICU bed, ventilation system capable of both invasive and non-invasive modes, with the possibility to apply several respiratory support techniques, is required.
3	For each NICU bed, at least 16 electrical outlets, connected to both the main power supply and an emergency backup system, are required.
4	For each NICU bed, a minimum of 3 oxygen outlets, 3 compressed air outlets, 3 vacuum outlets and 4 data network ports are required.
5	For each NICU bed, at least 2 volumetric pumps and 3 infusion pumps for parenteral and enteral nutrition, as well as medication administration, are required.
6	For each NICU bed, multiparametric monitor, including pulse oximetry and transcutaneous CO_2 monitoring, is required.
7	Each NICU bed must be integrated in a centralized alarm system.
8	For each NICU bed, systems for invasive blood pressure monitoring are required.
9	For each NICU bed, EEG monitoring system, and where possible, amplitude-integrated EEG (aEEG), is required.

1.3. Reconfiguration of the Neonatology and NICU

The NICU of the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico is part of the Neonatology and Neonatal Intensive Care Unit, a clinical complex structure organized into eight functional areas, as reported in Table 1.6, that together cover the spectrum of neonatal and perinatal care.

Table 1.6: Functional areas of the Neonatology and NICU

1	Terapia Intensiva
2	Terapia Subintensiva
3	Nido 1 (General newborn nursery)
4	Nido Solventi (Private newborn nursery)
5	Area di Day Hospital, Ambulatoriale e Follow up
6	Servizio di Medicina Fisica e Riabilitativa Pediatrica
7	Centro di Nutrizione a Partenza Neonatale
8	Attività di Consulenza Psicologica

In 2024, the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico recorded a total of 6,094 births, reflecting a slight increase from the 6,088 births in 2023. Within this setting, the Neonatology and Neonatal Intensive Care Unit oversaw 824 hospitalizations in its Intensive and Sub-Intensive areas, a volume slightly lower than the 841 admissions recorded in the previous year. Despite this small reduction in absolute numbers, the clinical complexity of cases remains high: a total of 97 neonates admitted weighed less than 1,500 grams at birth, and 74 were born at or before 30 weeks' gestation. Although surgical activity decreased in 2024, with 60 surgical patients compared to 74 in the previous year, and 94 procedures performed versus 114 in 2023, the unit maintained high standards of care. This is supported by a reduction in mortality rate, with 17 deaths recorded in 2024 compared to 27 in 2023. At the same time, the bed occupancy rate remained consistently high, reaching 94.3% in the NICU, further confirming the unit operational capacity and the importance of its role in delivering intensive neonatal care [21]. Following the regional authorization issued on May 18, 2012, the NICU, currently located on the first floor of the Mangiagalli Clinic, was expanded to a total of 23 beds. These are distributed across four dedicated rooms, consisting of a 10-bed open bay room known as TIN 1, which is reserved for the most critically ill neonates, a 6-bed open bay room known as TIN 2, intended for those in less critical condition who

nonetheless require neonatal intensive care, a 5-bed open bay room called TIN 3, primarily used for neonates requiring surgical care, and an area that includes 2 isolation rooms [22]. However, this organizational model is set to be replaced as part of a broader institutional redevelopment. The Neonatology and NICU will be relocated to the Padiglione Sforza and reorganized across three floors, as outlined in Section 1.1.1. Altogether, the new unit will comprise 142 bassinets, distributed to preserve the flexibility required by clinical demands. These include 24 beds assigned to neonatal intensive care, 36 beds for sub-intensive care, 27 beds for neonatal admission, and 55 nursery beds. The distribution of these resources has been designed not only to increase capacity, but also to enable smooth transitions between different levels of care, in line with a model based on graded intensity. Located on the second floor of the Padiglione Sforza, the NICU area will encompass a total of 44 beds, all organised in single or double patient rooms, each equipped with advanced structural and technological systems, as detailed in Section 1.2.2.2. Among these, 24 beds are reserved for the most critical neonatal patients, requiring full respiratory support, intensive metabolic management, and invasive hemodynamic monitoring, with a standard of at least 600 minutes of nursing care per patient per day. In addition to these, 20 beds will be functionally designated for sub-intensive care, although they will be co-located within the NICU area and will share the same high-level infrastructure. This sub-intensive group is further divided by clinical use: 10 of these beds, located in the Central Plate, will be allocated to post-surgical neonates who remain clinically complex but stable, while the other 10 beds, situated in the South Block, will be dedicated to patients in clinical descalation (neonates who are improving but still require close monitoring and specialized support). In both cases, the standard of care will include at least 300 minutes of nursing care per patient per day. Beyond the NICU area, a dedicated Sub-Intensive Neonatal Unit (SubNICU area) will house an additional 16 sub-intensive care beds, which, while offering a slightly lower level of surveillance and clinical support compared to the 20 sub-intensive beds located within the NICU area, are intended for neonates who have reached a degree of clinical stability but are not yet ready to transition to general neonatal care. Within the same space, 6 additional beds are available for sub-acute neonatal patients who are approaching discharge or transfer to lower acuity wards, thus supporting a step-down model of care. This allocation of lower-acuity beds, as shown in Table 1.7, both within the NICU area and the SubNICU area, enhances flexibility and continuity of care by allowing neonates to remain in familiar clinical environments as their conditions evolve, thus creating a system capable of adapting to the changing needs of each patient [23].

Table 1.7: Classification of beds by level of care and area of allocation within the new Neonatology and NICU

	Intensive	Sub-intensive	Ward	Nursery
NICU area	24	20	/	/
SubNICU area	/	16	6	/
Nursery – 3rd floor	/	/	12	35
Postpartum ward	/	/	7	/
Nursery – 6th floor	/	/	2	20
Total	24	36	27	55

The new NICU area is structured into modular care units of 4 to 6 beds, each supported by a dedicated nursing station. Each room exceeds 7 square meters per bed and is fully equipped with high-technology systems, including mechanical ventilators, real-time monitoring devices, and space for parental presence. One of the units will be equipped with a variable pressure system, designed to provide infectious isolation. To support the complex patient profiles managed within this area, the unit is equipped with advanced diagnostic and therapeutic technologies, including two-dimensional and Color Doppler ultrasound, continuous EEG and NIRS monitoring, computerized pulmonary function assessment, and both invasive and non-invasive ventilation systems. A neonatal ECMO platform is also available. All care activities are fully integrated into a centralized electronic medical record system, which allows real-time documentation, medication management, and interdisciplinary coordination. Recognized for its clinical expertise, technological advancement, and integrated care model, the NICU has been designated by Regione Lombardia as a STEN hub, a neonatal ECMO center, and the Regional Coordination Center (CCR) for inherited metabolic diseases, confirming its status as a national and international center of excellence.

1.4. Alarm management in Intensive Care Units

In Intensive Care Units (ICUs), where critically ill patients require constant monitoring and immediate intervention, clinical alarms represent an essential component of patient surveillance systems. These alarms are automatically generated by IT systems that process data from sensors monitoring vital parameters such as heart rate, arterial blood pressure, and oxygen saturation, with the purpose of alerting healthcare professionals whenever a physiological value exceeds pre-set thresholds (clinical alarm) or when a device malfunction occurs (technical alarm) [24]. In principle, alarms are designed to enhance patient safety by enabling timely responses. In practice, however, the overwhelming number of alarms, up to 700 per patient per day, poses a significant risk to both patients and staff. Evidence shows that between 72% and 99% of these alarms are either technically false, triggered by artefacts or motion, or clinically non-actionable. This alarm overload leads to what has been widely defined as alarm fatigue, a condition of sensory and cognitive saturation that impairs the ability of healthcare staff to detect, evaluate, and respond appropriately to alarms. Nurses, who provide continuous bedside care, are particularly exposed to this phenomenon, which undermines clinical judgment and reduces situational awareness. Alarm desensitisation may lead to delayed responses, inappropriate adjustment of alarm settings, or complete deactivation, behaviours that have been shown to jeopardize patient safety. Between 2009 and 2012, 98 adverse events related to missed alarms were reported in the United States, 80 of which were fatal. Moreover, excessive exposure to alarms contributes to a persistently noisy environment, with ICU sound levels often ranging from 47 to 77 dB, above the 35 dB limit recommended by the World Health Organization [25][26]. While modern monitoring systems offer more precise and varied data, they also produce more frequent and redundant alarms: IT systems currently in use lack adequate positive predictive value, often failing to distinguish between meaningful events and technical noise. Additionally, the issue of alarm fatigue does not arise from a single cause; rather, it is the result of a complex interaction between device settings, clinical protocols, human behaviour, and organisational culture. Despite its critical relevance, alarm fatigue remains a poorly standardised domain. A wide range of strategies has been explored to mitigate the problem, including staff training, development of alarm management protocols, adjustment of threshold parameters, and implementation of predictive algorithms, but no universally effective solution has emerged. The Emergency Care Research Institute (ECRI) and The Joint Commission (TJC) have consistently recognised alarm management as a

critical priority in patient safety. TJC has included “safe use of alarms” among its National Patient Safety Goals for 2025, calling for system-level improvements to guarantee that alarms are effectively perceived and promptly addressed [27]. The importance of implementing an efficient alarm management system in intensive care units derives from their inherently complex nature. In the case of the NICU, this complexity results from the critical condition of its target population, as described in Section 1.2.2.1, and from the structural and technological features, as detailed in Section 1.2.2.2. In such a setting, the governance of clinical alarms emerges as a central priority, requiring a robust, well-designed system capable of ensuring timely interventions and reducing alarm fatigue, consequently improving patient safety.

Chapter 2 | Study outline

2.1. Impact of the transition

As previously discussed, the New Building of the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico represents a milestone in the hospital's structural and organizational redevelopment plan, aimed at addressing emerging healthcare needs through advanced technological solutions and innovative models of care. Within this framework, the complete reorganization of the NICU constitutes one of the most impactful interventions, both from a technological and an organizational point of view. This transformation goes far beyond a mere redistribution of physical spaces. The primary objective is to increase the quality of care by ensuring continuity across all levels of clinical intensity, avoiding unnecessary patient transfers, and adapting the environment to the specific conditions of each newborn. This approach is rooted in the principles of patient-centered design, risk mitigation, and integrated technological support, creating a safer, more efficient, and clinically responsive setting [28]. The core element of this transition is the new alarm management system. Thanks to its introduction, a series of concrete benefits are achieved on multiple levels. From a clinical perspective, the reduction of non-significant alarms and the greater reliability of notifications improve patient safety, lowering the risk of losing relevant alerts. At the same time, newborns benefit from a quieter and less stressful environment, which favors rest, while families experience higher levels of satisfaction with the care provided [29][30]. These improvements also produce important financial returns, since they contribute to shortening the average length of stay and reducing adverse events that often prolong hospitalization [31][32][33]. On the operational side, the benefits are equally evident. Healthcare professionals report greater satisfaction, improved productivity, and reduced stress, thanks to a significant decrease in alarm overload and cognitive fatigue. The optimization of alarm management also enables a more efficient use of nursing resources, reducing the time wasted in responding to non-significant alarms and allowing staff to focus on direct patient care [34][35][36][37]. The effectiveness of these benefits lies precisely in the dual nature of the system, which combines technological innovation with organizational reconfiguration. On

the technological front, there is the implementation of a Distributed Alarm System (DAS), compliant with IEC 60601-1-8 international safety standards, that enables bidirectional communication between multiparameter monitors, the central monitoring station, the notification server, and mobile devices assigned to clinical staff. This ensures integrated, secure, and standardized alarm management, reducing informational noise and increasing the clinical relevance of alerts [38]. From an organizational perspective, the transition requires a review of clinical workflows and the integration of operational tools to support healthcare professionals, including:

- Mobile devices enabling remote alarm management and monitoring, delivering near real-time notifications of changes in vital parameters, and allowing request forwarding in accordance with delegation and escalation protocols.
- Delegation and escalation protocols designed to optimize task distribution and ensure prompt specialist intervention, safeguarding patient outcomes.

2.1.1. Technological domain

The technological reorganization of the NICU is supported by the adoption of the Philips Pic iX platform combined with Event Notification services. Its architecture represents a substantial evolution compared to traditional centralized monitoring systems, as it is based on a distributed multi-server model, where each server is assigned a dedicated function. This modular approach ensures both scalability and resilience, since the malfunction of one server does not compromise the functioning of the entire system but only temporarily affects the specific services hosted on that component. At the core of this distributed architecture, displayed in Figure 2.1, there is a set of specialized servers, each responsible for key functionalities:

- Primary Server
  This server constitutes the backbone of the system. It is responsible for hosting the licenses that enable the monitoring of all connected beds, up to a total capacity of 1600. It manages the topology of the hospital network, the configuration of clinical departments, and the centralized distribution of monitoring devices. Furthermore, it stores patient demographic information and baseline clinical control data. By concentrating these functions, the Primary Server allows the infrastructure to grow in a modular way,

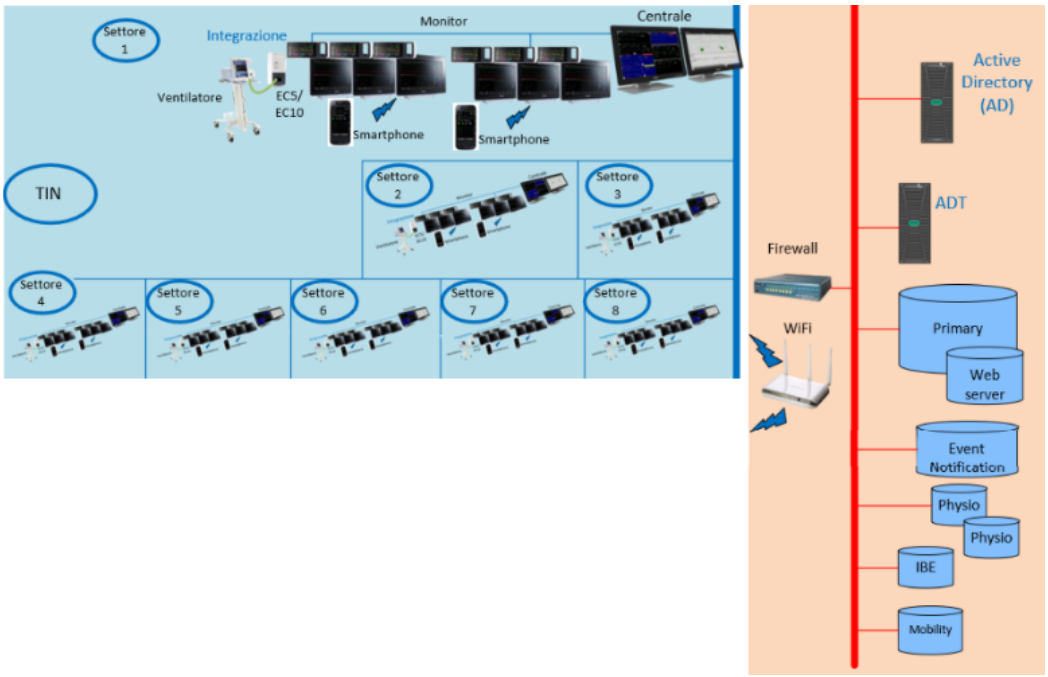
progressively activating additional beds while maintaining uniformity and central control.

- Web Server
  This module is designed to grant access to patient data through standard web browsers, without the need for additional applications. It allows clinicians to consult both current data and retrospective clinical records for one or more patients. In the architecture adopted for the NICU, the Web Server role is assigned to the same virtual machine as the Primary Server, an optimization that reduces hardware consumption without sacrificing access to essential functions.
- Notification Server
  This component is dedicated to the management of alarms and clinical notifications sent to mobile devices. When an alarm is generated at the bedside, the Notification Server ensures that the information is transmitted in real time to the smartphone of the healthcare professional responsible for that patient. Thanks to this functionality, continuous surveillance is guaranteed even in mobility, and the staff can intervene promptly. The server supports advanced escalation mechanisms, ensuring that if an alarm is not acknowledged, it can be redirected to another operator or escalated according to predefined clinical protocols.
- Physio Server
  The Physio Server is responsible for archiving high-frequency physiological data. Each instance can manage up to 128 beds, storing up to seven full days of disclosure of all patient parameters. This functionality allows clinicians to review events retrospectively, analyze trends, and document clinical reports with complete datasets. It also separates the workload between administrative and configurational tasks (in charge of the Primary Server) and the storage of large volumes of clinical data.
- Mobility Server
  This module supports the Care Assist Mobile application. Through this application, healthcare professionals can receive alarms and consult patient data in near real time directly on their smartphones or tablets, whether they are moving between wards or working in Silent Rooms.
- IntelliBridge Enterprise (IBE) Server
  This server functions as the integration broker between the Philips environment and third-party hospital applications. It ensures interoperability through internationally recognized standards, such as HL7,

and manages interfaces with systems like Active Directory (AD) and Admission-Discharge-Transfer (ADT). Thanks to IBE, Pic iX provides a single integration point, simplifying connectivity and guaranteeing that patient demographic data and user profiles are always aligned with the hospital information systems.

- PerformanceBridge Focal Point
  This platform is dedicated to the monitoring of the technological infrastructure. It manages the inventory of devices, generates alerts and operational statistics, and supports the application of security patches at the operating system and application level. It also allows visualization of key performance indicators through dashboards and summary reports. By providing proactive monitoring and maintenance tools, PerformanceBridge Focal Point increases the reliability and security of the entire infrastructure.

Figure 2.1: System technological architecture



Each of these servers is virtualized in a VMware ESXi environment, with high availability features such as clustering of virtual machines, vMotion, and Storage vMotion. These technologies ensure that the system can continue to function even in case of hardware failure or during scheduled maintenance operations. For example, if the Primary Server is unavailable, the monitoring stations in the wards switch to local mode, maintaining the recording of clinical data and resynchronizing once the central server is restored [39]. The network infrastructure that connects

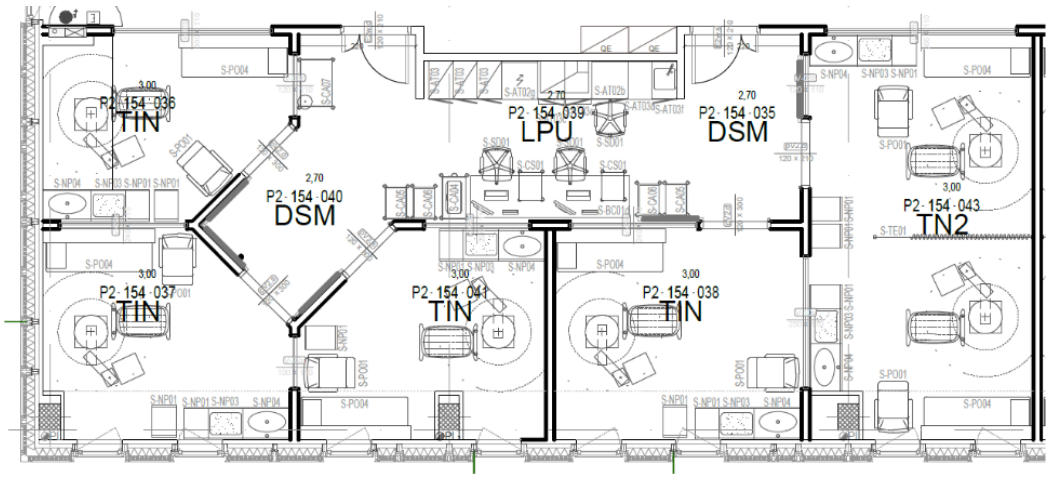
these servers and devices is the IntelliVue Clinical Network (ICN), a dedicated clinical network developed by Philips for secure and reliable communication between monitoring systems. The ICN is compliant with IEC 80001-1 standards on risk management in medical IT networks and is implemented through VLANs, access control lists, DHCP, and DNS services. This ensures both isolation from other hospital traffic and the ability to integrate with the broader IT environment. Wireless networking plays a key role, as it enables the mobility features of the system. For this reason, strict requirements are established for the Wi-Fi infrastructure, which must guarantee adequate coverage, bandwidth, and interference management to ensure the timely delivery of alarms to mobile devices. Another fundamental element of the technological architecture is compliance with the IEC 60601-1-8 standard, which regulates the safety and reliability of clinical alarm systems. The system qualifies as a Confirmed Distributed Alarm System (CDAS), meaning that alarms are not only transmitted but also require confirmation and acknowledgment by the receiving operator. This bidirectional mechanism ensures that every alarm is managed according to strict protocols, prevents the risk of unhandled events, and supports escalation if an operator does not respond [38]. The adoption of a CDAS enables the introduction of Silent Rooms, a central innovation of the NICU project. Acoustic alarms are eliminated from patient rooms, protecting the newborn from unnecessary noise and reducing stress levels for both infants and staff. In conclusion, the system constitutes a complex technological ecosystem, specifically designed for neonatal intensive care. Its distributed architecture combined with strict adherence to international standards and the integration of mobility and Silent Rooms, transform this complexity into operational efficiency, ensuring reliable alarm management, enhancing patient safety, and optimizing clinical workflows.

2.1.2. Organizational domain

On the organizational domain the most significant changes revolve around two interrelated elements: the allocation of mobile devices to clinical staff, and the establishment of delegation and escalation protocols for alarm management. These elements translate technological potential into daily practice, ensuring that alarms are handled efficiently, reliably, and without ambiguity. A key organizational innovation is the systematic use of smartphones assigned to nursing staff. Unlike generic mobile phones, these devices are preconfigured with the Pic iX platform and equipped with the Care Assist Mobile application. Each smartphone is not a generic

communication tool but a true clinical workstation in pocket format, capable of receiving alarms in near real time, displaying waveforms and numerical values, and allowing the nurse to accept, delegate, or escalate notifications according to predefined protocols [40][41]. The devices are mapped to precise clusters of beds. In the Mangiagalli NICU configuration, the model is based on groups of three beds. Each group is assigned one dedicated smartphone, ensuring that alarms generated by those three beds are always routed to the nurse responsible for that cluster. This one-to-one mapping between physical patient groups and devices prevents confusion and overlaps, while providing immediate accountability. The organizational logic extends further by introducing redundancy. For every group of beds, a backup smartphone is also foreseen, so that in case of device malfunction, loss, or battery discharge, coverage is not interrupted due to purely technical causes. With the integration of smartphones into workflows, nurses are no longer expected to rely exclusively on acoustic alarms at the bedside but instead use mobile notifications as the primary source of information. This paradigm requires organizational discipline, as every professional must be confident that alarms assigned to their device fall within their direct responsibility. It also requires training and adaptation, since the device becomes a continuous extension of the nurse's clinical activity. The physical space of the NICU is organized into sectors, each consisting of two groups of three beds. Structurally, as showed in Figure 2.2, every bed is placed inside an individual box, so that each sector is composed of six separate boxes, all accessible from a pre-room area where the central monitoring station of the sector is located.

Figure 2.2: Layout plan of a sector



Within this configuration, every group of three boxes is assigned to a dedicated nurse, who is equipped with a smartphone configured for alarm management. Each sector therefore includes two nurses and two mobile devices. For safety and continuity of care, sectors are paired with one another, so that each has a designated backup sector ready to provide support in case of local overload or unacknowledged alarms. The introduction of Silent Rooms represents one of the most significant organizational and cultural changes. In every isolated box, particular emphasis has been placed on mitigating acoustic pollution for both patients and staff. Literature consistently demonstrates that silent environments are beneficial for the recovery and stability of neonates and premature infants. For this reason, the acoustic alarms generated by patient monitors inside each box are normally deactivated, while visual alarms remain active on the monitor screen. Likewise, ventilator alarms, once integrated with the monitoring system, are silenced locally. In the future, incubators and infusion racks may also be integrated following the same logic, further reducing acoustic disturbance within the patient environment. Thanks to this complete remotization of alarms, those, generated by both monitors and ventilators, remain silent inside the patient boxes, while acoustic and visual alerts are fully active at the sector's central desk and on mobile devices [42]. Patient monitors are configured with a bed-to-bed view, enabling access to the parameters and alarms of all six patients in a sector from each box, thus allowing staff to promptly assess the overall clinical situation. To safeguard privacy, especially given the presence of families, the parameters of other children become visible only when the operator selects the corresponding pre-configured tab, while alarm notifications remain active and are indicated by a blinking tab in case of critical events. Alarms generated by monitors, which in the NICU under consideration are Philips devices, can be acknowledged and silenced either from mobile devices, from the central station, or directly at the bedside monitor in accordance with delegation and escalation protocols, whereas alarms from ventilators or other integrated third-party devices can be acknowledged centrally but silenced only at the device itself, in compliance with regulatory requirements. Building on this configuration, the operational workflow is further supported by structured delegation protocols, which define how responsibility for alarm management is shared among staff members. Within this organizational structure, delegation protocols operate at two levels:

- First-level delegation allows a nurse to reassign an alarm to a colleague in the other group of the same sector, typically when the primary nurse is already engaged in a critical procedure and cannot respond immediately. If

the nurse does not activate the busy mode on the Care Assist Mobile application, delegation occurs automatically after a predefined time interval set in the system configuration. By contrast, if the busy mode is enabled, the system delegates the alarm instantly, without any delay [40].

- Second-level delegation extends responsibility beyond the sector, activating the paired backup sector so that colleagues in the adjacent unit can intervene if alarms remain unacknowledged within a predefined timeframe.

Escalation protocols, by contrast, are activated in emergency conditions. When an alarm indicates a potentially life-threatening situation, the system automatically forwards the notification beyond the nursing team, directly involving the physician. From an organizational point of view, escalation introduces an additional safety net, creating a chain of responsibility that starts with the bedside nurse and extends to higher levels of clinical authority. In this way, the organizational framework of the NICU transforms alarm management into an accountable and resilient process. The complexity of neonatal intensive care is thus met with a structured organizational response, where technology and workflows converge to ensure that every alarm is acknowledged and resolved as quickly as possible, safeguarding both patient safety and staff performance.

2.2. Pilot study

The introduction of a new alarm management system within the NICU, combined with the broader reorganization of both spaces and workflows, represents a transformation of exceptional magnitude. The transition cannot be approached as a mere technical upgrade; it is instead a fundamental redesign of how alarms are generated, transmitted, received, and acted upon in one of the most delicate care environments, as emerges from Section 1.2.2.1. Because of this, it is neither safe nor prudent to move directly from the current system to full-scale implementation in the new building without a prior step of validation. A pilot study becomes a necessary element of the transition, as it allows the NICU to anticipate the effects of change, to assess the interplay of technology and organization under real operating conditions, and to identify both the benefits and the difficulties that would otherwise emerge only after definitive relocation. The study consists of two steps: in the first step, the actual alarm management system is used to establish baseline performance and conditions; in the second step, the new alarm management system is implemented, allowing for comparison and assessment of the impact of the new configuration. The decision to run the pilot in the present NICU, specifically in TIN 2 and TIN 3, is strategic. These areas are less critical compared to TIN 1 and provide an environment in which the post-transition configuration can be safely simulated, allowing the impact of the system change to be understood and adjustments to be made in advance. One of the principal benefits expected from the pilot is the identification of behavioral patterns. Until today, alarms have been an acoustic presence in the NICU, with staff conditioned to respond to sounds and bedside visual signals. Shifting this responsibility to smartphones, structured delegation, and escalation rules represents a radical change. In practice, it is possible that staff may delay acknowledging alarms when occupied with procedures, that escalation mechanisms may be used too frequently or not at all, or that certain features of the system may be bypassed if they are perceived as inefficient. By observing actual behavior in the pilot will these patterns emerge. The pilot also offers a gradual introduction of staff to the new workflow. Change of this magnitude cannot be imposed overnight. Without preparation, sudden implementation would risk disorientation, confusion, and potentially unsafe conditions. Therefore, the pilot acts as a tool to acquire familiarity and expertise that will later be valuable for the broader roll-out. Another decisive advantage of the pilot is that it allows the collection of measurable evidence. During the pilot, indicators such as the number of alarms generated per bed, the average response time, the frequency of delegation

and escalation, and the percentage of alarms resolved within given timeframes can be tracked. In addition, qualitative feedback from staff will provide insights into usability, cognitive load, and overall satisfaction. These data will not only confirm the system's effectiveness but also identify areas for improvement, supporting decisions for its final implementation on the basis of real evidence rather than assumptions. Despite these advantages, the pilot also comes with important challenges. The most immediate technical challenge is the installation of mobile devices and their integration into daily workflows. Smartphones must be configured, secured, and distributed in a way that ensures reliability and avoids additional burdens for staff. Beyond this, the broader IT infrastructure requires a substantial update. The alarm management system is based on the Philips monitoring system, which currently serves not only the NICU but also several other critical care units. To enable the pilot, it is indispensable to update the software release of the central monitoring system and to upgrade all multiparameter monitors equipped with the integrated license. This requirement means that the pilot cannot be contained within the NICU alone. In practice, this involves more than sixty monitored beds across the hospital: 23 in the current NICU, 10 in the Sub-TIN, 12 in the adult ICU, 8 in the Cardio-ICU, and 9 in the Neuro-ICU. The need to anticipate the upgrade, originally planned for the move into the new building, to enhance the pilot ongoing, introduces an additional layer of difficulty, as it accelerates technical activities and imposes new demands on IT and Clinical Engineering teams.

2.3. Thesis objective

Within the context of the transition and the pilot study described above, this thesis sets out to provide a structured evaluation of the new alarm management system in NICU. The goal is therefore not merely to describe the outcomes of the pilot, but to establish a methodology for assessment, capable of identifying the strengths, weaknesses, and broader implications of the transition in practice. The distinctive contribution of this work lies in the design of an evidence-based framework for assessment, aimed at collecting, analyzing, and interpreting data in order to evaluate the actual impact of the new alarm management solution. This approach ensures that decisions regarding full implementation will be grounded in measurable evidence rather than assumptions. In particular, the thesis pursues the following objectives:

- To define the domains of investigation required to explore the technological and organizational implications of the new alarm management system.
- To develop a data collection tool, capable of capturing perceptions and usage patterns from clinical staff exposed to the new setting.
- To establish a method of data analysis, transforming raw information into evidence that can inform decisions for the final configuration of the system after relocation.

The ultimate aim is to conduct a structured assessment of the alarm management system, to evaluate the real impact of the transition, identify risks to be minimized, and support the gradual adaptation of staff to the new operational workflow. To this end, the thesis adopts a semi-quantitative questionnaire as data collection tool. This method achieves a balance between quantitative analysis and qualitative insights, merging the potential to derive statistical data with the capacity to understand subjective feelings and subtle behaviours that are crucial for evaluating complicated socio-technical systems like alarm management in intensive care. The assessment design relies on a two-stage survey strategy, in which a pre-questionnaire is conducted before the transition to establish a baseline condition of the existing alarm management system, while a post-questionnaire, structured around the same domains, is carried out after the pilot study onset. This parallelism makes it possible to attribute differences between the two datasets to the effects of the transition, ensuring a robust evaluation of impact against the baseline.

2.4. The working group

The implementation of a new alarm management system in the Neonatal Intensive Care Unit requires the collaboration of multiple stakeholders, each bringing specific expertise. To this end, a dedicated working group was established, involving the Neonatology and NICU, the Information Systems, the Clinical Engineering and Philips S.p.A., representing the clinical, technical, and industrial partners. As previously outlined in Chapter 1, the Neonatology and NICU is a complex reality composed of multiple functional areas. Within this broader structure, the pilot project specifically involves the NICU area, which represents the most critical care setting for newborns. The participation of NICU staff is central to guarantee the success of the pilot. Both medical doctors and nurses are actively engaged, since the introduction of the new alarm management system affects their daily workflows in different but complementary ways. Physicians contribute by validating clinical priorities, setting alarm thresholds, and testing the new workflow in critical scenarios. Nurses, as the primary operators of the system, play an even more central role by continuously managing alarms and directly experiencing the shift from traditional bedside acoustic alerts to remote notifications. Through their involvement, the pilot not only tests the technical functionality of the platform but also investigates the behavioral adaptation of clinical staff, highlighting strengths and potential barriers before the effective full-scale implementation. Additionally, the Information Systems provides the technological infrastructure for the implementation and deployment of the new alarm management system. In the pilot, and more broadly throughout the transition, its role is to ensure that the Philips system operates within a stable and high-performance environment, which is essential both to enable the required functionalities and to guarantee compliance with hospital IT policies and cybersecurity standards. In particular, Information Systems is responsible for:

- Server virtualization and hosting, ensuring that each component of the distributed architecture (Primary, Web, Notification, Physio, and Mobility servers) runs on reliable virtual machines with high availability features.
- Network configuration and management, with particular focus on the IntelliVue Clinical Network (ICN). This involves VLAN segmentation, access control, and quality of service to safeguard the timely delivery of alarms across the infrastructure.

- Wireless coverage, guaranteeing that smartphones used by clinical staff can receive notifications seamlessly in all areas of interest.
- Interoperability with hospital systems, managing the integration of the platform with services such as Active Directory and ADT.

Philips S.p.A. is the technology supplier of the project and brings to the pilot not only the hardware and software components required, but also a set of solutions and services designed to transform the way clinical alarms are managed. Within the pilot, Philips is responsible for providing and setting up the distributed system architecture, as well as enabling the Care Assist Mobile application. Philips' role, however, goes beyond technology. The company also supports the hospital during the adoption phase by offering training and consultancy. Through dedicated sessions and educational materials, Philips helps prepare physicians and nurses for the new workflow. In addition, the PerformanceBridge Focal Point environment provides monitoring and reporting tools that make it possible to track alarm traffic and system performance over time. In summary, Philips plays a dual role in the pilot: on the one hand as the technology supplier, ensuring the availability and reliability of the platform, and on the other as an active partner, supporting training, consultancy, and performance monitoring. In the framework of introducing the new alarm management system in the NICU, also Clinical Engineering plays a crucial role as a technical-operational link between the technology provided by the industry and the clinical needs. Its role is not limited to ensuring compliance with standards or the correct integration of devices, but above all to making the concrete implementation of the solution both feasible and sustainable within the hospital setting. Clinical Engineering supports the installation process, coordinating the activities required to prepare the technological infrastructure. Specifically, these include updating the servers, replacing the hardware of monitoring hubs where necessary, and upgrading all existing monitors licensed with the Philips platform to ensure full compatibility with the new alarm management system. In addition, according to ECRI's Health Devices evaluations and the FDA MAUDE database, engineers may identify known alarm-related hazards, past incidents, and device vulnerabilities, integrating this evidence into the configuration process. This systematic approach helps avoid the adoption of technologies with critical alarm deficiencies and establishes objective criteria for implementation [43]. Finally, Clinical Engineering support the staff training, clarifying subtle but critical device-specific differences in alarm logic and functionality. By reinforcing correct alarm use, engineers ensure that new systems are not only technically integrated but also clinically understood and effectively managed. Through this combination of

technical implementation, evidence-based device assessment and staff education, Clinical Engineering transforms the introduction of the new alarm management system from a mere technological upgrade into a structured safety initiative. The result is an integrated model in which technology and clinical practice converge to improve patient safety, reduce alarm fatigue, and optimize workflows in the NICU.

Chapter 3 | Methodology

3.1. Design of the semi-quantitative questionnaire

The design of the semi-quantitative questionnaire represents an important stage of this research, as it enables the development of a tool capable of systematically and reliably capturing the technological and organizational dimensions impacted by the introduction of the new alarm management system. Considering the complexity of the situation being examined and the consequences for patient safety and care process efficiency, it was deemed essential to use an evidence-based method, ensuring that the questionnaire is developed on reliable scientific foundations rather than on unproven assumptions. To this end, the identification of the domains of investigation and the variables to be included was informed by a Systematic Literature Review, conducted in accordance with the internationally recognized PRISMA guidelines [44]. This process ensured methodological rigor, transparency, and reproducibility in the selection and analysis of sources [45]. Therefore, the outcome was a tool developed on published evidence, but also adjusted to the specific conditions of the Neonatal Intensive Care Unit of the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico. In this way, the questionnaire preserves its general validity, and at the same time responds to the contextual requirements identified during the preliminary analysis.

3.1.1. Systematic Literature Review

According to Cochrane, a Systematic Literature Review (SLR) is a review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review [45]. This definition underlines two essential features of the method: the explicit formulation of a research question and the adoption of transparent, reproducible procedures that minimise bias and maximise the reliability of conclusions. Unlike narrative or descriptive reviews, which may provide a broad overview but lack methodological rigour, the SLR represents an evidence-based approach designed to synthesise knowledge in a structured and critical manner [46]. The adoption of a systematic literature review in this project is

primarily justified by its direct role in shaping the semi-quantitative questionnaire. Instead of depending on assumptions or context-specific impressions, the review offers a solid foundation of evidence that helps identify the key domains to be investigated. Specifically, this process assists in determining which domains are deemed important in the examination of similar conditions and how these domains are explored in self-report instruments. In this sense, the SLR serves as a systematic link between current scientific understanding and the necessary criteria for designing questionnaires, ensuring coherence, reliability, and adherence to established standards. The Research Question guiding the SLR is formulated as follows:

"*In Neonatal Intensive Care contexts adopting single-box organisational models and remote alarm management systems, which dimensions are explored through self-reported instruments to evaluate the perceived effectiveness and the operational challenges of the clinical surveillance system?*"

Starting from this question, the review makes it possible to identify recurring domains such as staff cognitive load, usability of alarm notification systems, noise levels, and perceived patient safety, while also bringing attention to underexplored areas such as family experience or escalation protocols. Through this methodology, a tool can be developed. The latter is not only scientifically robust but also structured to capture change over time, as outlined in Chapter 2, Section 2.3. For this reason, the questionnaire is structured in two parts, allowing the comparison of differences between the two distinct alarm management system models. To conduct the systematic review, a stepwise process is followed, beginning with the definition of inclusion and exclusion criteria and continuing with the selection of databases, search strategies, and subsequent phases that are described in the following sections.

3.1.1.1. Inclusion and exclusion criteria

On this basis, the search for evidence is initiated by defining inclusion and exclusion criteria, both general and specific, which serve as a framework for identifying and selecting the studies to be included in the review. Establishing these criteria is a fundamental step to ensure transparency and methodological rigour, as it makes the selection process reproducible. A distinction is made between general and specific criteria. The general criteria are independent of the topic under investigation and refer to formal aspects of the publications, such as the year of

release, the language of the article, and the accessibility of the full text. Their purpose is to guarantee the clarity, and availability of the evidence considered, regardless of the content of the study [47]. The general inclusion and exclusion criteria are reported in Table 3.1.

Table 3.1: General inclusion and exclusion criteria

General Inclusion Criteria	General Exclusion Criteria
The article is published after 2005 (included)	The article is published before 2005
The article is written in English	The article is not written in English
The article is full accessible online	The article is not full accessible online

The specific criteria, on the other hand, are directly related to the content of the studies and to their relevance for the research question. They define which types of clinical settings, technological infrastructures, and methodological approaches are pertinent to the analysis, and which should be excluded [47]. In this way, the review focuses on studies that investigate self-reported instruments in Neonatal Intensive Care Units, particularly in relation to single-room organisational models, alarm management technologies, and perception-based outcome measures. Table 3.2 and Table 3.3 report respectively the specific inclusion and exclusion criteria applied.

Table 3.2: Specific inclusion criteria

Specific Inclusion Criterion	Explained reason
Studies conducted in NICUs with single-room configurations or decentralized patient layouts	Ensures comparability with the physical and operational model of the new NICU, where patient care is delivered in individualized rooms, limiting direct line-of-sight supervision and requiring distributed alarm management.
Studies that implement or analyze mobile alarm notification systems (e.g., smartphone apps, wearable alerts, nurse handhelds)	Relevant to understanding how alarms are managed remotely from the point of care, as in the CareAssist system used at Mangiagalli, which enables alarm visualization and silencing on mobile devices.
Studies that assess centralized or distributed alarm infrastructures	Focuses on system-level integration (e.g., between monitors, servers, and mobile platforms) comparable to the technological stack

integrated with bedside monitoring systems	used in the new NICU (PIC iX, Notification Server, Physio Server).
Studies using self-reported methods (e.g., questionnaires, surveys, Likert scales, structured interviews) to collect clinician perceptions on the system	Ensures methodological alignment with the pilot study, which relies on structured self-report tools to capture operators' subjective evaluations of the alarm management system. These methods are essential to understand how comparable studies structure and administer perceptual data collection in similar NICU contexts.
Studies that evaluate specific perception-based outcome dimensions (e.g., alarm fatigue, perceived urgency, usability, trust in alarm systems, reactivity, or workflow-related stress)	Focuses on identifying which outcome domains are typically assessed in similar studies and which perception-based KPIs (e.g., perceived safety, alarm responsiveness, delegation effectiveness) can be adapted to the post-pilot evaluation of organizational and technological impact.

Table 3.3: Specific exclusion criteria

Specific Exclusion Criterion		Explained reason
Contextual mismatch		The study does not specifically focus on neonatal intensive care units, or addresses them only tangentially, thereby limiting its relevance for evaluating the NICU-specific care model under investigation
Broad discussion		The study refers to organizational and/or technological aspects, workflows, or alarm systems, but addresses them in a general or non-specific manner, lacking detailed analysis or measurable outcomes
Not available abstract - NAA		The abstract of the study is not available, preventing evaluation of relevance
Not elsewhere	Economic analysis	The study focuses primarily on cost-related evaluations (e.g., cost-effectiveness, cost-benefit, or budget impact analyses), prioritizing financial

classified - NEC		metrics and economic modeling without directly assessing outcomes of interest
	Parent-targeted study	The study investigates outcomes related primarily to parents (e.g., stress, satisfaction, bonding, mental health), without directly assessing what is of our interest
	Technical discussion	The study discusses architectural or environmental aspects such as alarm systems, lighting, sound, or room layout, but focuses on their technical function or design rather than assessing what is of our interest
	Patient-targeted study	The study focuses on clinical outcomes related to the infant's physiological parameters (e.g., heart rate, oxygen saturation, laboratory values), without addressing what is of our interest

The integration of general and specific criteria establishes a dual-level framework that ensures a systematic, transparent, and goal-oriented selection of studies.

3.1.1.2. Search strings and databases

The next step of the SLR concerns the identification of the databases to be consulted and the formulation of search strategies consistent with the research question [47]. To ensure coverage and reliability, three major scientific databases are selected: PubMed, Scopus and Web of Science. The choice of these sources allows for a comprehensive search across both biomedical literature (PubMed) and multidisciplinary scientific contributions (Scopus and Web of Science), thus reducing the likelihood of omitting relevant studies. The focus is on studies examining Neonatal Intensive Care Units with different architectural models, specifically comparing single-room (single-family or private room) with open-bay (open ward or shared room) configurations. In PubMed, the search strategy combines Medical Subject Headings (MeSH) with free-text keywords. MeSH is a controlled and hierarchically structured vocabulary developed by the National Library of Medicine, which ensures the retrieval of all articles indexed under a given descriptor, regardless of the terminology adopted by the authors [48]. The addition of free-text terms complements this by capturing studies that explicitly contain

those terms in the searchable fields, thus including articles that may not be indexed under the corresponding MeSH descriptor. The query used is:

("Intensive Care Units, Neonatal"[Mesh] OR "NICU" OR "neonatal intensive care") AND ("single room" OR "single-family room" OR "private room") AND ("open bay" OR "open-bay" OR "open ward" OR "shared room").

Differently, in the other two bibliographic databases, where MeSH terms are not available, the search is carried out using only free-text keywords, with the following query:

("neonatal intensive care" OR "NICU") AND ("single room" OR "single-family room" OR "private room") AND ("open bay" OR "open-bay" OR "open ward" OR "shared room").

In Scopus, the search is restricted to title, abstract, and keywords, while in Web of Science it is extended to all fields. The combined use of PubMed, Scopus, and Web of Science, each with tailored search strategies, provide a solid foundation for a thorough and reproducible literature search. From the application of the search strings across the three selected databases, a total of 254 records were retrieved: 62 from PubMed, 86 from Scopus, and 106 from Web of Science. All retrieved records were exported into an Excel file that served as the dataset for the review. The file was structured to include multiple attributes, each corresponding to a specific column. Table 3.4 provides a detailed description of the dataset structure.

Table 3.4: Structure and description of the dataset used for SLR.

Excel Column	Description
Progressive number	Progressive number assigned to each record to ensure unique identification within the dataset.
Document type	Classification of the publication type (e.g., article, book chapter, conference paper, editorial, meeting abstract, proceedings paper, review).
Document database	Database from which the record was extracted (PubMed, Scopus, or Web of Science).
Document language	Language in which the publication was written.
Document authors	List of authors credited in the publication.
Document title	Title of the publication.
Publication year	Year in which the publication was released.

Publication journal	Name of the publication journal, included to allow for the retrieval of its Scimago Journal Rank (SJR) classification.
Document details	Details, including publication year, publication journal, volume, issue number, and citation count.
DOI	Digital Object Identifier, a unique alphanumeric string that permanently identifies the publication.
Abstract	Summary of the content of the publication.
Duplicated	Indicator specifying whether the record is a duplicate of another already retrieved.
SJR Quartile at publication	SJR quartile classification of the journal at the time of publication.
Last SJR Quartile	Most recent SJR quartile classification of the journal.
H-index	The h-index indicates the journal's number of publications (h) that have been cited at least h-times. It enhances the quantification of journal scientific relevance.
Screening input	Indicator specifying whether the record is considered during the screening phases.
General Round Screening	Preliminary assessment of pertinence: decision resulting from the general inclusion/exclusion criteria application
1st Round Screening	1st assessment of pertinence: decision resulting from the first round of screening.
2nd Round Screening	2nd assessment of pertinence: decision resulting from the second round of screening.

At this stage, only a subset of attributes was automatically populated by the databases, namely: progressive number, document type, document source, document language, document authors, document title, publication year, publication journal, document details, DOI, and abstract. All the other fields were progressively completed according to the methodological steps described in the following sections.

3.1.1.3. Duplicate removal strategy

A duplicate removal strategy was applied to reduce redundancy in the dataset and to establish a coherent set of records for further analysis [47]. Because the same publication can appear in more than one bibliographic database, duplicate entries were identified during the data organization phase. Each record was assigned a

binary label within the attribute Duplicated, classifying it as either unique or copy. The unique label was assigned to the first occurrence of a publication, while all additional identical instances were labeled as copy. In total, 133 duplicates were identified across the databases. After their removal, the dataset was reduced from 254 records to 121 unique publications. From this point onward, the SLR proceeded by considering exclusively these unique records, which served as the basis for the subsequent screening phases.

3.1.1.4. Source quality assessment

The quality of each document was evaluated in accordance with the quality of the journal in which it was published. Two bibliometric indicators were considered: the SJR quartile (both at the year of publication and at the present) and the H-index of the journal. The Scimago Journal Rank (SJR) indicator represents the average number of weighted citations received in a given year by documents published in the selected journal during the previous three years. Citations are weighted according to the prestige of the citing source, so that those received from highly ranked journals contribute more than those from less influential ones. Journals are ranked according to their SJR value and then divided into four quartiles within each subject category, with Q1 representing the highest values and Q4 the lowest. For the purpose of this review, the SJR quartile corresponding to the year of publication of each article and the most recent quartile available were both extracted. Alongside the SJR quartile, the H-index of the journal was also recorded. The H-index combines productivity and impact, since a journal has an H-index of h if h of its documents have each received at least h citations. From this definition, it can be inferred that high H-index values indicate sustained scientific relevance over time [49]. On the basis of these indicators, each article was given a preliminary quality label. The decision rule established that articles published in journals classified in Q1 or Q2, either at the year of publication or at present, were accepted; those published in Q4 were rejected; and those in Q3 were accepted only when the H-index of the journal was greater than 80. In cases where bibliometric information was not available (NA), a conservative approach was applied, and the article was accepted. The decision rule adopted is formalized in the following formula:

= IF (OR (M2[4]="NA", N2[5]="NA", O2[6]="NA"), "ACCEPT (NA – conservative)",

[4] SJR quartile at year of publication
[5] Current SJR quartile
[6] Journal H-index

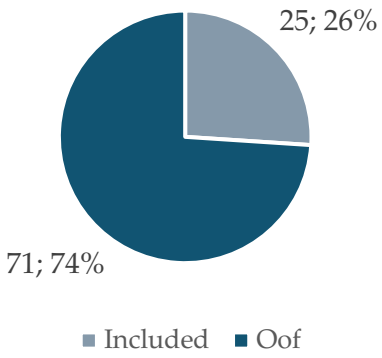
IF(AND(M2<="Q2", N2<="Q2"), "ACCEPT",
IF(OR(M2="Q4", N2="Q4"), "REJECT",
IF(OR(M2="Q3", N2="Q3"), IF(O2>80, "ACCEPT", "REJECT"),"REJECT"))))

Additionally, for journals classified under multiple subject categories, the SJR quartile for the year of interest was calculated as the average of the quartiles across the different categories, and this value was used in the assessment. At this point, 100 records remained. Subsequently, the screening proceeded according to the general criteria already discussed and reported in Table 3.1. The application of these criteria resulted in the exclusion of four articles: three were not accessible and one was published in 1999. The language filter did not lead to any further exclusions, as the two articles in French had already been removed as duplicates, while the article in German had been excluded because it was published in a journal below the required quality threshold. Consequently, 96 articles were retained and constituted the input for the subsequent phase: the first-round screening.

3.1.1.5. First round screening: title and abstract

The first-round screening was conducted through the examination of the titles and abstracts [47] of the 96 records retained from the previous step. Each record was carefully reviewed to assess whether it met at least one of the predefined inclusion criteria for potential eligibility. Articles that did not meet any inclusion criteria were classified under one of the exclusion categories and subsequently removed from further consideration. The inclusion and exclusion criteria applied during this stage are summarized in Tables 3.2 and 3.3, which have been previously presented and discussed. As a result of this process, 25 studies satisfied at least one inclusion criterion and were retained for the next phase, whereas 71 were excluded as "Out of focus." The overall distribution of included and excluded records is shown in Figure 3.1, where approximately one quarter of the articles (26%) were retained, while the remaining 74% were excluded.

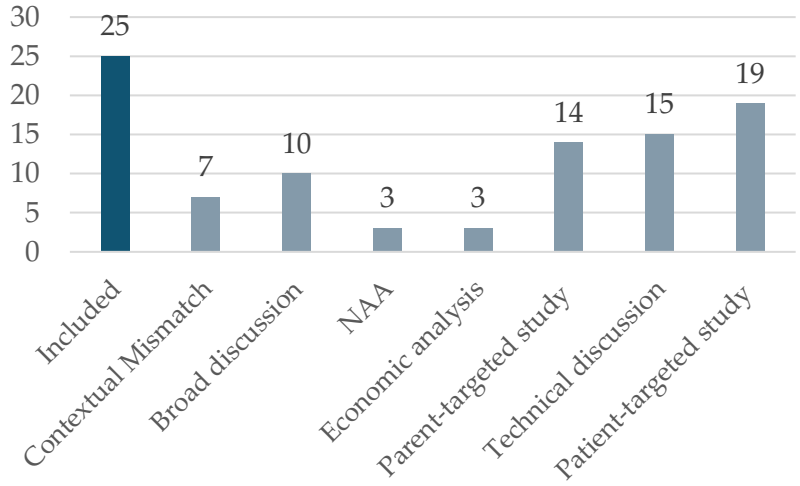
Figure 3.1: Overall proportion of included and excluded records in the first-round screening.



As shown in Figure 3.1, this initial screening acted as a filtering step to refine the focus by excluding irrelevant instances, retaining only those pertinent and capable to ensure alignment with the research objectives. The excluded records comprised studies that, while related to neonatal care contexts, did not specifically focus on neonatal intensive care units or addressed them only marginally. Others lacked sufficient methodological depth, presenting general discussions of organizational or technological issues without detailed analysis or measurable outcomes. A further share of exclusions involved records for which the abstract was unavailable, preventing a proper assessment of their relevance. This represents a potential limitation of the screening process, as the absence of an abstract may lead to the exclusion of studies that could, in principle, be pertinent. In this case, however, exclusion was maintained since the number of records falling into this category was minimal (3) and unlikely to influence the overall results. Finally, a significant portion of the excluded studies fell within the "Not Elsewhere Classified (NEC)" group, which encompassed research that, although methodologically sound and often detailed in scope, did not align with the analytical focus of this review. These studies addressed themes related to neonatal care or intensive care environments but approached them from perspectives that were not directly relevant to the evaluation of the NICU care model and its impact on system efficiency. Within this group, economic analyses typically compared the cost implications of different NICU configurations, such as Single-Family Room versus Open Bay layouts, using cost-effectiveness, cost-benefit, or budget impact frameworks. While these studies provided valuable insights into financial and economic dimensions of neonatal care, they primarily emphasized monetary and resource-related outcomes without linking them to operational performance or the broader systemic efficiency

dimensions that constitute the focus of the review. Parent-targeted studies, on the other hand, focused on the experiences, emotions, and perceptions of parents of neonates, exploring aspects such as stress, satisfaction, bonding, and mental health. Although these dimensions represent an important component of family-centered care, they fall outside the analytical framework adopted in this study, which primarily examines the interplay between organizational and technological domains and their effects on system-level outcomes. Analogously, technical discussions examined aspects of NICU architecture and technology, such as lighting, acoustics, alarm systems, and spatial organization, mostly from an engineering or design perspective, without linking them to system performance. Lastly, patient-targeted studies were primarily focused on clinical or physiological outcomes for infants—such as heart rate, oxygen saturation, or laboratory parameters—emphasizing medical and biological aspects rather than the organizational or technological domains influencing system efficiency, and were therefore not considered within the scope of the present review. A detailed distribution of these excluded records across the different exclusion categories is presented in Figure 3.2, which highlights the relative weight of each type of misalignment.

Figure 3.2: Distribution of excluded records by exclusion category during the first-round screening.

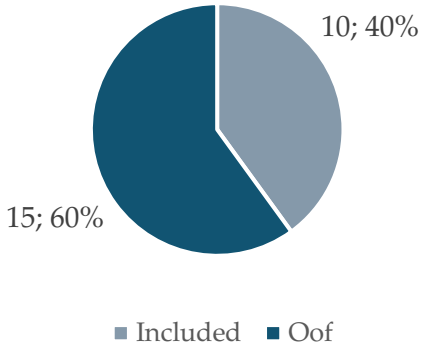


3.1.1.6. Second round screening: full-text

Following the preliminary title and abstract assessment, the second-round screening consisted of the full-text review [47] of the 25 studies retained from the previous phase. This step aimed to ensure a more accurate and comprehensive

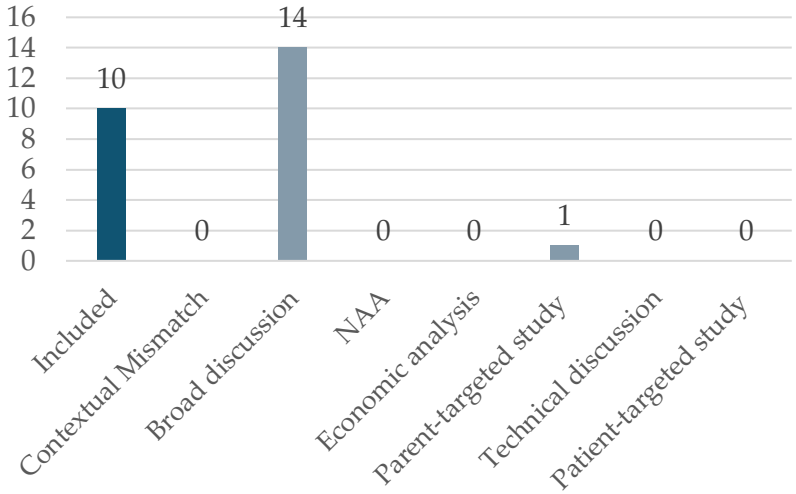
evaluation of each study's actual relevance to the objectives of the review. As a result of this in-depth screening, 10 studies were confirmed as eligible for inclusion, while 15 were excluded. The overall outcome of this process is shown in Figure 3.3, which indicates that 40% of the studies were included and 60% were excluded.

Figure 3.3: Overall proportion of included and excluded records in the second-round screening.



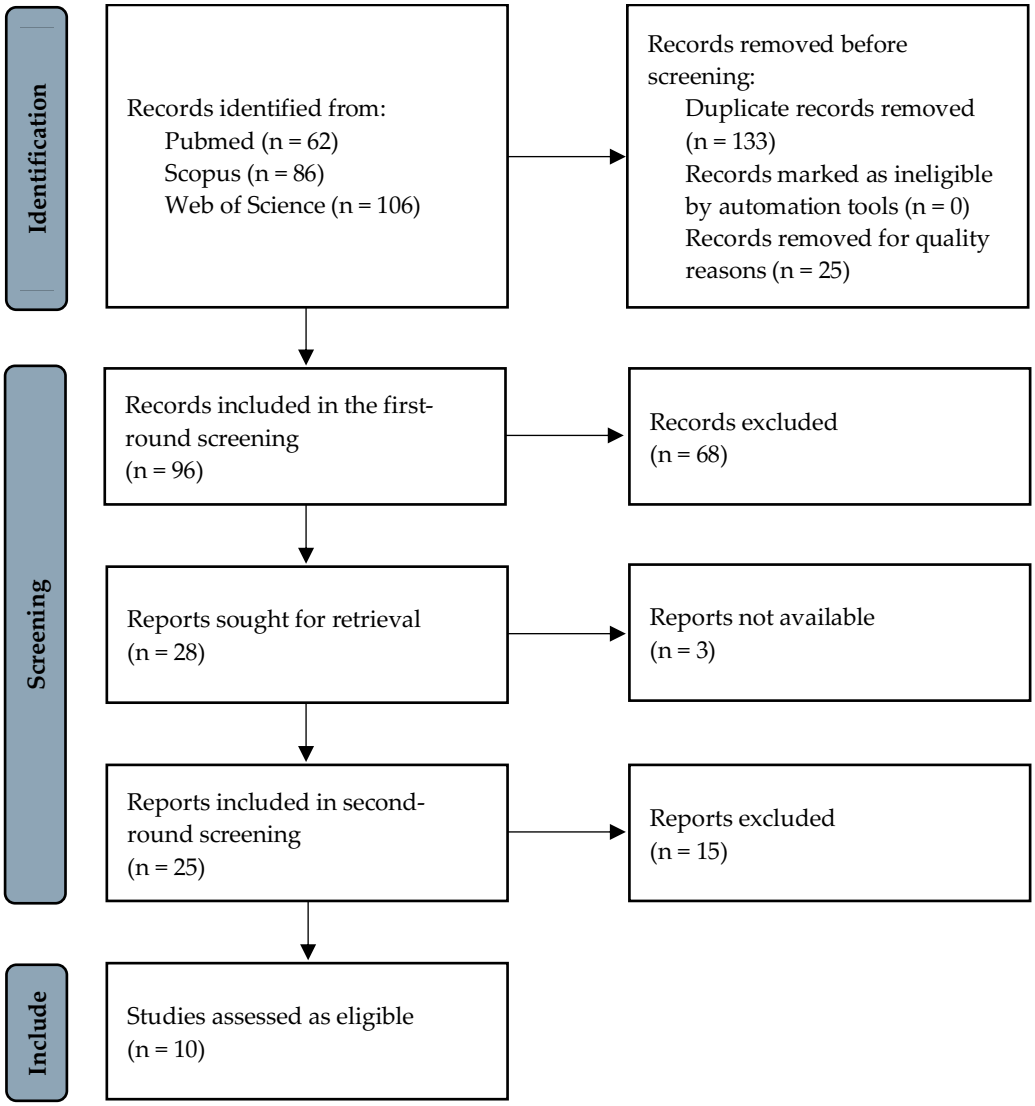
As illustrated, a significant reduction in the number of eligible studies was observed at this stage, reflecting the higher level of rigor applied during the full-text evaluation compared with the previous round. A detailed distribution of the excluded studies by exclusion category is presented in Figure 3.4. Most of the excluded records (14) fell under the Broad Discussion category, as they addressed organizational or technological aspects in a general or non-quantitative manner, without providing the analytical depth required by the review.

Figure 3.4: Distribution of excluded records by exclusion category during the second-round screening.



Overall, the second-round screening allowed for a substantial refinement of the dataset, resulting in a final selection of 10 studies that demonstrated alignment with the aims of the review. A summary of the entire review process up to this stage is presented in Figure 3.5.

Figure 3.5: PRISMA 2020 flow diagram for new systematic reviews which included searches of databases



It is important to highlight that during the full-text analysis, it was observed that several of the ten included studies cited additional papers that were not part of the initial dataset. Some of these cited studies were further examined, as their content proved to be highly relevant to the objectives of the review. Given their conceptual alignment and their specific contribution to the development of the self-report questionnaire for assessing the new alarm management system, six of these studies were subsequently added into the final pool of selected articles. Consequently, a

total of sixteen studies were retained as the final output of the systematic literature review.

3.1.1.7. Data Extraction Form

The Data Extraction Form (DEF) is an organized tool created to methodically gather all important information from the studies that are part of the review. Generally, the DEF consists of information such as the study's identification, the study's design, characteristics of the population, tools for measurement, areas of investigation, outcomes, and principal findings [47]. In this review, it was used to record the self-reporting tools, also referred to as instruments, employed in the eligible studies, to identify the domains investigated by each tool, and to extract the corresponding items, also referred to as questions, used to explore each domain. In other words, the DEF facilitated the extraction of the investigated domains and the corresponding items required to examine them. Each of the sixteen selected studies was examined with the aim of analysing the self-reporting instruments used to evaluate operators' working system in neonatal intensive care environments. This examination revealed that several studies had used the same validated questionnaires, sometimes slightly modified or focused on specific subscales. Therefore, a total of ten unique self-reporting instruments were identified. For each tool, the domains of study were recognized, and each specific item was mapped within its corresponding domain. Upon reviewing each tool, it was noted that certain questionnaires explored similar fields. To consolidate this data, all areas related to comparable topics were categorized together under a unified conceptual heading. In conclusion, the domains extracted correspond to those reported in Table 3.5.

Table 3.5: Domains extracted through DEF

Investigative Domains
Interaction with the physician
Interaction with other nurses
Decision making
Nurse stress
Nurse satisfaction
Work organisation
Work efficiency

Colleague support
Non-nursing tasks
Technologies and tools usability
Equipment condition
Equipment availability
Stocked material
Work environment
Family burden
Security and privacy level
Noise level
Light level

Furthermore, since each question was mapped to its corresponding domain within each tool, it was possible to determine how every domain is investigated across the literature. Like the domains, items that pertain to the same domain, conceptually alike and that come from different tools were made uniform. In conclusion, by conducting this process, it is offered a thorough and cohesive synthesis of the current research environment [50-65], as shown in Table 3.6, enabling the recognition of pertinent domains of inquiry and the related questions utilized to examine them. This represents the result of the SLR.

Table 3.6: Mapping of questions to investigative domains

Domain	Item	Question
Interaction with the physician	1	I believe that communication with physicians is clear, collaborative, and free from conflicts, and that clinical information provided is adequate to ensure effective patient management.
	2	In my unit, I believe that there are structured opportunities and a supportive environment that facilitate constructive discussion among healthcare professionals, including operational and clinical aspects.
Interaction with other nurses	1	In my unit, I believe that there are structured opportunities and a supportive environment that facilitate constructive discussion among healthcare professionals, including operational and clinical aspects.
	2	In my work setting, I believe that relationships with nursing staff are collaborative and free from significant conflicts or barriers to cooperation.

	3	During shift handovers, I receive clear and complete clinical information needed to ensure continuity and safety of care.
Decision making	1	During my clinical activity, I sometimes experience uncertainty or lack of preparation in complex situations, such as the use of specialised equipment or managing the informational and emotional needs of patients and families.
	2	In my work environment, I perceive a climate that promotes professional growth, supported by an adequate staffing level and strong team motivation.
	3	I sometimes experience stress when I have to take responsibility for complex clinical decisions, especially in situations where medical support is not immediately available.
Nurse stress	1	I am usually able to perform my professional activities in the different work areas (e.g., patient rooms, medication areas, documentation zones) without frequent interruptions from other staff members or external factors.
	2	During my work shift, I often perceive a hectic and tense environment that affects my level of operational stress.
Nurse satisfaction	1	I often feel satisfied with the work environment in which I operate.
Work organisation	1	During my shift, the overall organisation of work (staff coverage, patient assignment, availability of support, and access to operational resources) has hindered my ability to provide timely, safe, and effective nursing care.
	2	I often experience fatigue related to the work environment.
Work efficiency	1	From the workstations in my unit, I can easily monitor the clinical status of my patients.
	2	The design of the unit (layout, spaces, and workstations) supports my operational efficiency and the quality of care I can provide.
	3	I believe that the unit design supports the quality of care, facilitating both routine activities and emergency interventions.
	4	The unit design (layout, spaces, workstations) facilitates skin-to-skin contact.
	5	I believe that the unit design helps me maintain control over the risk of adverse events.
Colleague support	1	During my shift, I can rely on colleagues with an adequate level of experience and availability, also thanks to a spatial organisation that promotes collaboration.

Non-nursing tasks	1	During my shift, I often have to perform activities that are not strictly nursing-related (e.g., administrative or bureaucratic tasks), taking time away from direct patient care.
Technologies and tools usability	1	I sometimes feel uncertain or insecure when using some of the complex healthcare devices available in the unit.
Equipment condition	1	I sometimes use equipment that is not in optimal condition for effective use.
Equipment availability	1	The improper placement of equipment often forces me to waste time searching for it.
	2	When I need to use a workstation or a technological tool, I can easily find one available.
Stocked material	1	The central storage area is adequately supplied with the necessary materials and devices.
Work environment	1	The physical environment of the unit, particularly the workspace and stations dedicated to nursing activities, is adequate, flexible, and functional to my operational needs.
	2	The spaces dedicated to staff interaction (centralised or distributed nurse stations, patient rooms) are generally available and adequately equipped to support collaborative work.
	3	The spatial layout of the unit (e.g., distance between workstations and patient rooms, internal orientation) is functional and does not cause disorientation or excessive travel time.
Family burden	1	During clinical care, managing family members' needs requires significant effort and can represent a source of distraction, also depending on their level of readiness for discharge.
	2	The unit's organisation promotes parental presence and access to the newborn, ensuring adequate levels of privacy and opportunities to spend quality time together.
Security and privacy level	1	I believe that the unit ensures a safe environment for staff and provides adequate spaces to protect privacy during clinical and professional activities.
	2	The environmental conditions at the bedside allow for adequate privacy during skin-to-skin contact.
Noise level	1	The noise level in the unit is adequately controlled, so as not to disturb newborns and to ensure a favourable environment for both care and staff activities.

	2	The movement of people near patient stations is well managed and does not interfere with patient comfort or nursing activities.
	3	It is always clear and immediate to identify which patient an alarm refers to.
Light level	1	The level and quality of lighting in my unit promote both newborn wellbeing and an efficient, functional work environment for the staff.
	2	Lighting can be adjusted individually according to each newborn's clinical needs.

3.1.2. Customization on the two configurations

It is correct to consider the result of the systematic literature review as a semi-quantitative questionnaire fully based on scientific evidence. However, considering the intended use of this tool, it was deemed appropriate to carry out a targeted optimization aimed at developing the two pre- and post- versions to be administered according to the system configurations used in each specific phase of the pilot. As previously detailed, in the open-bay arrangement, alarm management operates under a centralizes system, and alerts from patient monitors and life-support equipment are announced at the central monitoring station as well as through the bedside devices themselves simultaneously. This design guarantees that alarms are easily heard throughout the unit, but it also creates constant background noise, which can result in alarm fatigue. Additionally, in this arrangement, the process depends on direct listening rather than organized communication methods. Every operator reacts mainly to sound signals and physical closeness, which might lead to uneven prioritization and mental strain. Considering the features of the existing alarm management system, the SLR-based questionnaire was tailored to create the initial version of the questionnaire, as outlined in Table 3.7. This version specifically addresses the operational and technological conditions observed during the first pilot phase. Thus, the evidence-based tool was tailored to fit the local environment, ensuring that its content matched the usual practices and reflected the system design typical of the initial phase of the pilot study.

Table 3.7: Pre-questionnaire

Category	Item	Question
Interaction with the physician	1	Communication with the physician is clear, collaborative, and free of conflict, and the clinical information provided is adequate for effective patient management.
Interaction with other nurses	1	Communication with the nursing staff is clear, collaborative, and free of conflict, and the clinical information provided is adequate for effective patient management.
Decision making	1	During clinical activity, I sometimes experience uncertainty or lack of preparation in complex situations related to alarm management.
Nurse stress	1	I am usually able to carry out my professional activities without frequent interruptions caused by alarms.
	2	What percentage of clinical alarms are clinically irrelevant?
	3	What percentage of technical alarms are clinically irrelevant?
Work efficiency	1	When I receive a clinical or technical alarm at the central station, and I am not engaged in patient procedures, I am able to respond promptly.
	2	When I am performing a procedure on a patient and receive an alarm at the central station, I am still able to promptly perceive whether it is necessary to intervene.
	3	The unit design facilitates the performance of skin-to-skin contact.
Technologies and tools usability	1	I sometimes feel uncertain when using technologies associated with alarm management.
Security and privacy level	1	The environmental conditions at the bedside ensure an adequate level of privacy for performing skin-to-skin contact.
Noise level	1	The level of noise generated by clinical and technical alarms in the unit is adequately controlled so as not to disturb infants and to ensure a favorable environment for both care and staff activities.
	2	The identification of the patient associated with an alarm is always clear and immediate.
Light level	1	The level and quality of lighting in the unit promote the infant's well-being and support a functional and efficient working environment for staff.

In contrast, the updated system introduced in the second pilot phase adopts a decentralized model in which alarms do not sound within the patient area but are instead directed to the sector's central station and simultaneously forwarded to the mobile device of the operator assigned to that patient. Considering the significant differences between the two setups, the SLR-based questionnaire was tailored to suit also this arrangement, resulting in the creation of the post-questionnaire version outlined in Table 3. 8.

Table 3.8: Post-questionnaire

Category	Item	Question
Interaction with the physician	1	The CareAssist interface allows clear communication of the clinical situation's severity, for example through the type of alarm, values, and notes.
	2	I receive a timely response from the on-call physician following an escalation.
Interaction with other nurses	1	After activating the BUSY mode or formal delegation, the alarms of my patients are usually taken over by a colleague, if available.
	2	I receive confirmation that a delegated alarm has been taken over by the colleague.
Decision making	1	When I receive a clinical alarm on the bedside monitor or via CareAssist, I am able to immediately assess its severity without interrupting the ongoing procedures.
	2	Technical alarms received through CareAssist or the central station are always understandable and clearly associated with the involved device.
	3	I feel I always have quick and clear access to the necessary clinical information, via CareAssist, the central station, or the monitor, to decide how to respond to an alarm.
Nurse stress	1	If I am unable to respond personally to an alarm, I still perceive a sense of urgency or mental pressure, even knowing that the alarm is visible and audible at the central station.
	2	When the frequency of alarms increases within a short time frame (5–60 minutes), I perceive a decrease in my promptness of response.
	3	The ability to consult parameters and alarms of other patients via the Bed-to-Bed function, from the bedside monitor, helps reduce the perceived impact of alarm fatigue.
	4	What percentage of clinical alarms are clinically irrelevant?
	5	What percentage of technical alarms are clinically irrelevant?

Work efficiency	1	When I receive a clinical alarm (from the monitor or ventilator) via CareAssist or the central station, and I am not engaged in patient procedures, I am able to respond immediately.
	2	When I am performing a procedure on a patient and receive a visual (silent) alarm on the bedside monitor or ventilator, I can still promptly perceive whether intervention is required.
	3	When I receive a technical alarm (e.g., a sensor disconnection or ventilator issue) through CareAssist or the central station, and I am not involved in patient procedures, I am able to respond immediately.
	4	The unit's design facilitates the performance of skin-to-skin contact.
Technologies and tools usability	1	I know when and how to activate the BUSY, formal delegation, and escalation functions on CareAssist, in order to redirect alarms respectively to the sector colleague, backup sector, or on-call physician.
	2	I can easily resume the management of my patients after deactivating the delegation.
Security and privacy level	1	The ability to consult parameters and alarms of other patients via the Bed-to-Bed function, from the bedside monitor, does not compromise the privacy of the remote infant.
	2	The environmental conditions at the bedside ensure an adequate level of privacy for performing skin-to-skin contact.
Noise level	1	I find it useful to be able to silence a clinical alarm via CareAssist, the central station, or the bedside monitor, depending on my current location.
	2	Although ventilator technical alarms cannot be silenced remotely, I am still able to manage them effectively and in a timely manner.
Light level	1	The level and quality of lighting in the unit promote the infant's well-being and support a functional and efficient working environment for staff.

It is important to note that the chosen areas examined, as indicated in Table 3.7 and Table 3.8, do not include all domains referenced in Table 3.6. This exclusion is justified because the research question specifically focuses on alarm management systems. The categories omitted were left out because they relate to wider environmental or personal factors that, while important for the overall quality of

work, do not directly pertain to the performance, usability, or efficiency of alarm management systems. Incorporating these elements may have diverted attention from the main objective of the study and introduced factors that were mainly designed to evaluate general working conditions instead of managing alarms. In the post questionnaire, due to the significant change caused by the establishment of the new system, that is intended for regular use and at the base of the operational efficiency in this high-demand care setting, an extra assessment tool was added: the System Usability Scale (SUS). This scale, already validated in existing research and acknowledged as a global benchmark for evaluating the usability of digital systems in clinical settings, allows for a numerical assessment of users' perceived ease of use, logical coherence, and assurance in system engagement, thus serving to evaluate the user experience [66][67]. Additionally, as noted in the large body of literature, a demographic section was incorporated into both versions of the questionnaire. This part gathers background details about the participants, including their gender, age, level of education, marital status and experience in ICUs. Moreover, an experience section was added to both versions to capture feedback on the questionnaire compilation experience. Finally, the questionnaires were evaluated by the heads of the NICU, who were actively engaged in the design process. Because of this collaborative review, the final version, showed in the Chapter 4, is closely aligned with the real context. In conclusion, the overall design process led to the creation of two tools that are both evidence-based and context-tailored, which together enhance the data collection in the two alarm management system configurations, the centralized and the distributed ones.

3.1.3. GDPR sensitivity and ethical consideration

Because the questionnaires are meant for the healthcare personnel of the NICU, the Data Protection Officer (DPO) of the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico has formulated a specific information notice. The document, prepared in accordance with the General Data Protection Regulation, EU Regulation 2016/679, and national laws on personal data protection, describes the purposes and methods of data processing, along with the measures taken to maintain confidentiality, integrity, and security [68]. It states that the gathered information will be utilized only for research and assessment related to the project, that participation is voluntary and relies on informed consent, and that no personal information will be disclosed to external parties. The complete information notice is presented below in Figures 3.6 and 3.7 in its original language.

Figure 3.6: Information notice - Page 1

Gentile Professionista,

in qualità di Istituto di Ricovero e Cura a Carattere Scientifico, la Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, secondo standard di eccellenza, persegue finalità di ricerca, prevalentemente clinica traslazionale e applicata nel campo biomedico e in quello dell'organizzazione e gestione dei servizi sanitari.
La SC Ingegneria Clinica intende condurre un progetto finalizzato a supportare il personale della SC Neonatologia e Terapia Intensiva Neonatale nella transizione al nuovo modello organizzativo e a valutarne l'efficacia complessiva.
A tal scopo è stato sviluppato un questionario volto ad analizzare le variazioni in termini di efficienza operativa, qualità percepita, usabilità, nonché a rilevare eventuali criticità e orientare l'adozione di azioni correttive da somministrare a tutto il personale afferente alla SC Neonatologia e Terapia Intensiva Neonatale.
Il questionario, realizzato per studiare modalità di prevenzione del rischio legato al setting del nuovo ospedale e alla tecnologia che verrà introdotta per gestire gli allarmi di monitoraggio, è stato creato con approccio evidence-based, supportato da una Systematic Literature Review (SLR) realizzata in conformità con le linee guida PRISMA.
Il questionario sarà suddiviso in due parti:

- una "PRE" che verrà fatta compilare prima di effettuare un upgrade sulle centrali di monitoraggio,
- una "POST" che verrà fatta compilare in due momenti diversi (ad un mese dall'upgrade e a due mesi).

Il questionario che Le chiediamo di compilare, e che trova di seguito, contiene una serie di domande che permetteranno al gruppo della SC Ingegneria Clinica l'individuazione di pattern comportamentali, esigenze specifiche e potenziali criticità, favorendo un'ottimizzazione data-driven della configurazione del sistema in ottica user-centered.
Congiuntamente alle risposte relative alle modalità di gestione organizzativa delle attività e delle strutture di allarmi, verranno raccolti anche dati di natura personale, utili per valutare aspetti correlabili allo stress, quali sesso, età (compresa in fasce), titolo di studio, etc…
A tal proposito, in conformità alla normativa vigente in materia di tutela dei dati personali (Reg. UE 678/2016 e D.Lgs 196/2003 come novellato da D.Lgs 101/2018), Le chiediamo di dare il consenso all'utilizzo dei suddetti dati, leggendo attentamente la presente informativa al trattamento.

I dati raccolti verranno trattati dalla Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, in qualità di Titolare del Trattamento, con la finalità di condurre l'indagine sopra descritta.
I dati raccolti verranno conservati presso la SC Ingegneria Clinica per il tempo necessario a condurre l'indagine. Trascorso tale periodo, i questionari verranno smaltiti e i dati cancellati.
I dati da Lei forniti non verranno condivisi con soggetti terzi ma rimarranno conservati unicamente presso la Fondazione.

Figure 3.7: Information notice - Page 2

Per procedere con la compilazione del questionario e aderire al presente progetto è necessario che Lei manifesti in modo libero, informato, specifico e inequivocabile il Suo consenso al trattamento dei propri dati personali che potranno così essere utilizzati per perseguire obiettivi di ricerca utili per l'avanzamento delle conoscenze in campo scientifico e dell'organizzazione e gestione dei servizi sanitari.

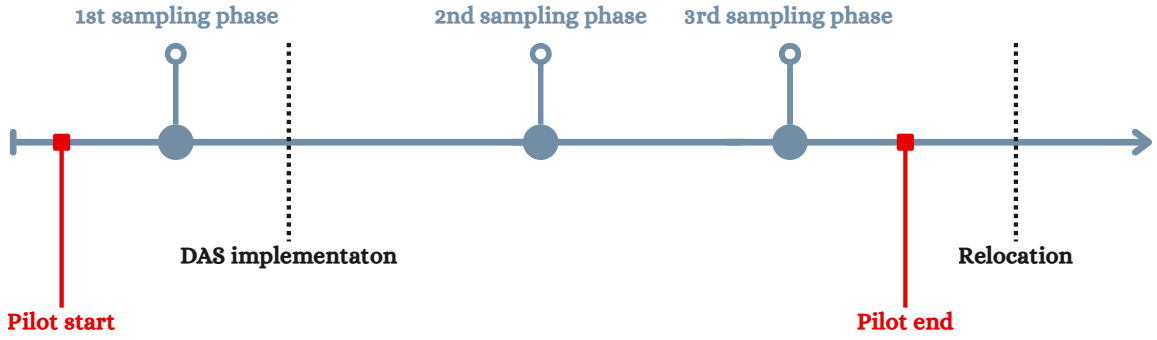
Qualora intenda ritirare il Suo consenso, o esercitare i Suoi diritti ai sensi degli artt. 15-22 del Reg. UE 679/2016 potrà darne comunicazione alla Fondazione al seguente indirizzo email: dpo@policlinico.mi.it

Alla luce di quanto sopra, con la compilazione del presente questionario, acconsente al trattamento dei dati da Lei conferiti, nei termini e secondo le modalità e per le finalità sopra descritte.

3.2. Administration strategy of the pre and post questionnaires

The two semi-quantitative questionnaires used in the pilot study were titled "pre" and "post" based on the particular phase of the pilot study during which they were given. Despite, both instruments have the same format and areas of investigation, they vary in their timing to capture how perceptions changed due to the transition to the new alarm management system. The pre-questionnaire was administered at the start of the pilot phase, during the first stage of data gathering (1st sampling phase), while the current setup of the NICU was still in use. At this point, the unit maintained its standard alarm system configuration, enhancing that this initial retrieval provides a reference point that reflects the normal operational state of the unit before any technological or procedural changes. Consequently, the system was upgraded to implement the Distributed Alarm System, simulating, within TIN2 and TIN3, the organizational structure that will characterise the unit after transfer. Therefore, two additional data collection points were scheduled, both utilizing the post-questionnaire. The first post-collection (2nd sampling phase), which is planned to occur within the first month following the system upgrade, is designed to enable the evaluation of immediate effects of the change and the early responses of the staff, while the second post-collection (3rd sampling phase), expected after two months, permits an assessment of the overall state once the system had been completely accepted into everyday practice. This three-phase model, displayed in Figure 3.8, creates a continuous framework that allows for the assessment of both the immediate and long-term effects of the new alarm management system.

Figure 3.8: Qualitative timeline of the pilot study phases.



3.3. Data analysis method

This chapter describes the methodology adopted for analysing the data collected via questionnaires, implemented by means of a code developed in Python language. The code functions as an analytical instrument that ensures the systematic, transparent, and reproducible processing of the data collected from participants' responses, progressively transforming raw data into interpretable user profiles. In practice, it supports the entire analytical process, from data preparation and coding to exploratory analyses and dimensionality reduction, and finally to the application of clustering techniques and statistical testing to assess differences between groups. In the following paragraphs, the reasoning and order of the implemented operations will be outlined in detail, highlighting the methodological choices and criteria that guide each phase, with the aim of ensuring scientific consistency, transparency, and the reproducibility of the analysis.

3.3.1. Data preparation and composite scores

The first section of the code establishes the analytical environment and outlines the basic framework for the entire process. Upon importing the required Python libraries and establishing the output directories, a collection of utility functions is presented to handle repetitive tasks like saving data, verifying integrity, aligning datasets, and labelling clusters. This initial stage creates a reliable computational foundation on which the actual data processing is developed. The focus of this script section is the data encoding phase, which converts the original questionnaire data, originally made up of textual categorical variables, into an ordinal format. Each column of the dataset is analysed and modified according to its characteristics. Demographic and background factors, including gender, age, education level, marital status, and work experience, are classified as categorical types. This indicates that they are qualitative characteristics presented through non-overlapping categories. Each of these variables is translated into an ordinal or binary system following established mappings: gender is represented as 0 for Male and 1 for Female; age goes from 0 ("Under 25") to 4 ("Over 55"); education and marital status are assigned ascending numerical codes that correspond to levels of attainment; finally, previous experience is represented as a binary variable, with 1 for "Yes" and 0 for "No". In contrast, aspects that measure attitudes and perceptions, like agreement levels, confidence or frequency, are regarded as numerical variables based on Likert-type scales. These are rated from 0 ("Strongly disagree") to 4

("Strongly agree"), which facilitates a numerical comparison among participants. The dataset additionally contains two percentage-based variables that measure the share of clinical and technical non relevant alarms. These are represented using a reverse ordinal mapping ("Less than 10%" equals 4, and "Over 90%" equals 0), ensuring that greater values mean more favourable situations. Following the encoding phase, the script undertakes a data aggregation process to create a collection of composite indicators that synthetise related items into more comprehensive attributes. Therefore, five composite scores (Score_1 to Score_5) are computed as the average of related items. To maintain a uniform interpretative direction, where higher values indicate more positive perceptions, reversed coding is applied to the items originally phrased in a negative form (q1 and q4), which refer respectively to situations of informational uncertainty in alarm management and lack of confidence in the use of alarm-related technologies. This adjustment ensures that all resulting scores follow the same "the higher, the better" logic, thus facilitating interpretation across dimensions. Furthermore, four additional questions related to the satisfaction of participants, covering clarity, relevance, completion time, and perceived usefulness of the tool, are grouped into the dedicated df_satis dataset. These questions are set aside from the primary analysis process and are solely intended to give general feedback to the questionnaire creators about the overall user completion experience. In summary, the dataset of interest (df_main) is made of two types of variable:

- Categorical variables: Gender, Age, Highest educational level, Marital status, and Experience in other intensive care units.
- Numerical variables: Composite scores (Score_1–Score_5).

The result represents a fully encoded and analytically coherent dataset that integrates both categorical descriptors and quantitative indicators, that serves as the working foundation for the subsequent phases of the project.

3.3.2. Exploratory data analysis

Subsequently, it is performed an Exploratory Data Analysis (EDA) aimed at evaluating the overall structure, quality, and internal consistency of the dataset before the implementation of reduction techniques [69]. The section begins with a normality assessment carried out through the Shapiro–Wilk test, which examines whether the numerical variables follow a normal distribution, returning, for each quantitative column, a W statistic and a p-value. Variables with $p < 0.05$ are

considered non-normally distributed, indicating deviation from gaussianity. Due to variables did not meet the normality assumption, it is confirmed the appropriateness of using non-parametric techniques in the subsequent analyses (e.g., Spearman correlations and Kruskal–Wallis tests). Following the normality check, a missingness analysis quantifies and visualizes the proportion of missing values across variables. The results are graphically represented in a heatmap (missing_heatmap.png) that reports the missingness pattern, allowing a rapid identification of incomplete data. The next step focuses on univariate analysis, which explores the statistical properties of each variable individually. For numerical variables, central tendency and dispersion measures (mean, median, standard deviation, interquartile range) are calculated, as well as shape indicators such as skewness and kurtosis. Moreover, potential outliers are detected through the interquartile range rule (values beyond 1.5×IQR from the quartiles). For categorical variables, frequency tables and corresponding bar plots provide an overview of the relative representation of each category. The bivariate analysis section investigates relationships between pairs of variables. For numerical variables, Spearman's rank correlation is computed, offering a non-parametric measure of monotonic association. The resulting matrix (spearman_corr_matrix.csv) and heatmap highlight the strength and direction of associations between composite scores. Variable pairs showing $|\varrho| \geq 0.80$ are reported separately (high_corr_pairs_ge_0.80.csv) as potentially redundant. Relationships between numerical and categorical variables are assessed through the Kruskal–Wallis test, a non-parametric alternative to one-way ANOVA, which evaluates whether the distribution of a numeric variable differs significantly across categories. Finally, associations between categorical variables are examined through Cramér's V coefficient, derived from the Chi-squared test of independence [69]. The combination of normality tests, missingness inspection, univariate summaries, and bivariate relationships provides a comprehensive understanding of the data foundation.

3.3.3. Dimensionality reduction techniques

After conducting the EDA, techniques for reducing dimensions were adopted to achieve a more concise representation of the dataset, while maintaining most of its information, offering a reduced set of orthogonal dimensions appropriate for future analyses. The first method implemented was the Principal Component Analysis (PCA), applied to the numerical variables combined with the one-hot encoded

categorical features [70]. The categorical variables were expanded into binary dummy indicators using the pandas.get_dummies() function. All variables were standardized by z-scoring through the StandardScaler class, ensuring unit variance and zero mean before decomposition. The explained variance ratio and its cumulative distribution was utilized to define the ideal number of components, selecting the smallest number that accounted for at least 80% of the total variance. The relevant component scores were extracted for additional analysis, and scree plots along with cumulative variance plots were created to illustrate the decline in eigenvalues, and therefore in variance explicated. Because the dataset is made of both numerical and categorical variables, another similar methodology applied is the Factor Analysis of Mixed Data (FAMD), performed using the prince library in Python. Quantitative variables are treated similarly to how they are managed in PCA, whereas qualitative variables are dealt with in the manner used in Multiple Correspondence Analysis (MCA) [71]. The analysis produced the component scores, eigenvalues, and graphical outcomes that were comparable to those obtained from PCA. For robustness reasons, the FAMD was replicated in R, using the FactoMineR package. Additionally, the PCAmix algorithm [72], implemented through the PCAmixdata library, was also executed in R, since no equivalent library is available in Python. With this approach, the comparison of the results obtained from these four dimensionality reduction techniques enables the assessment of the robustness and agreement of the extracted data structures.

3.3.4. Clustering

Following the dimensionality reduction phase, unsupervised clustering was utilized on the component scores derived from the PCA, FAMD (in Python and R), and PCAmix. The analysis utilized hierarchical agglomerative clustering as well as partitioning-based clustering (K-Medoids). In the hierarchical approach, three linkage criteria were considered (Ward, Complete, and Average) combined with two distance metrics: Euclidean and Manhattan. The analysis was executed iteratively for cluster numbers $K \in [2, 8]$, computing for each configuration the silhouette coefficient and the within intra-cluster dispersion. Both indexes were recorded and displayed to aid in recognizing the most stable clustering framework. Simultaneously, K-Medoids clustering was applied using the same range of K values and the same distance metrics. Unlike K-Means, this method minimizes the total pairwise dissimilarities by selecting actual observations as medoids instead of computing abstract centroids, which enhances robustness to outliers and non-

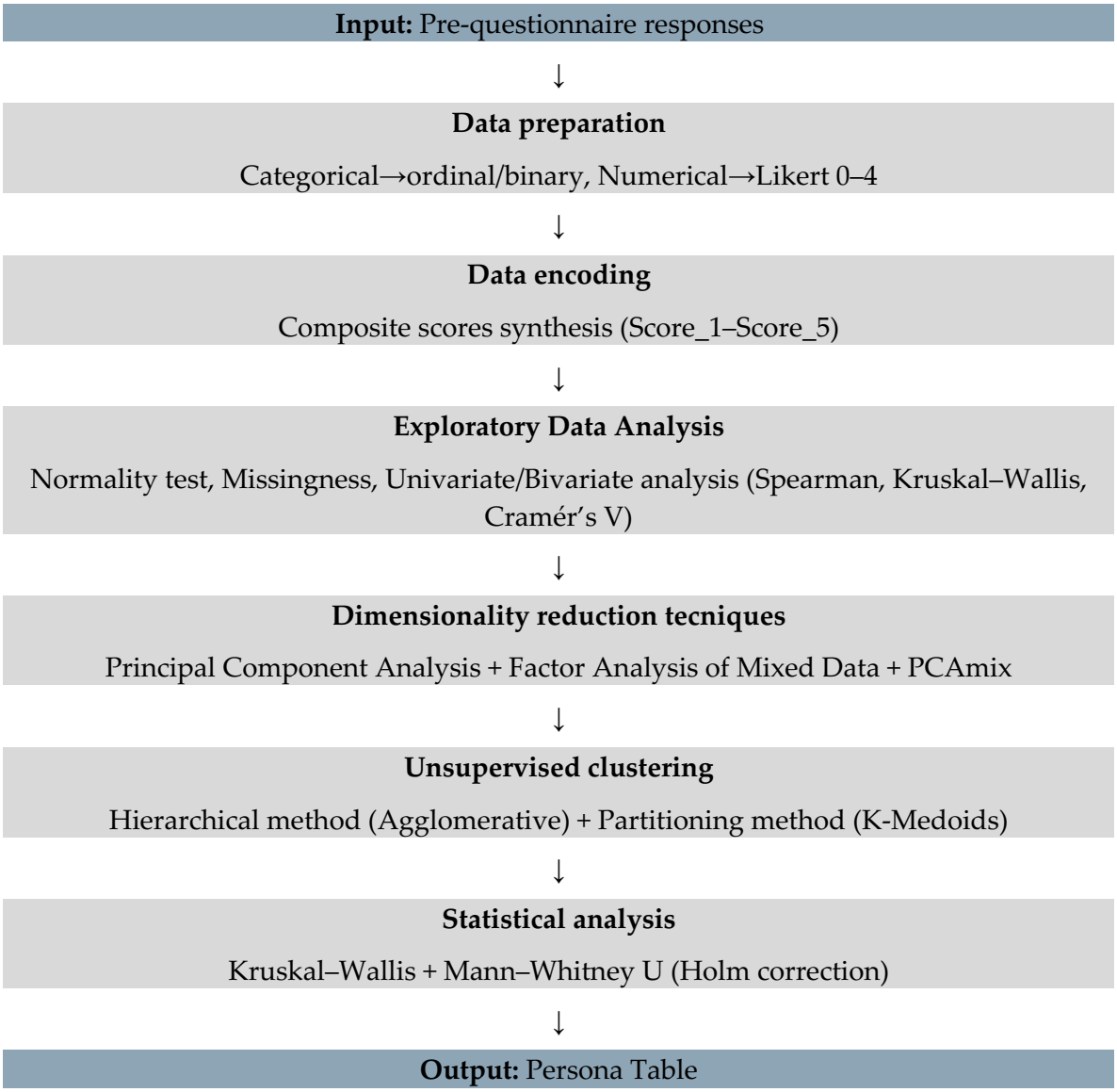
spherical cluster geometries. The implementation relied on a particular wrapper (_kmedoids_labels), which produced cluster assignments, silhouette scores, and within-cluster inertia for every configuration. Summary plots were created, illustrating the changes in the silhouette and elbow indices for each reduction method based on the value of K. All visual and tabular results were generated utilizing the matplotlib, pandas, and openpyxl libraries in Python. The clustering analysis, structured in this way, enables direct comparisons between the groups derived from various dimensionality reduction techniques (PCA, FAMD, FAMD_R, and PCAmix_R), aggregated with different clustering tools. This method allowed for assessing how consistently clusters appeared across different data representations, making it easier to recognize the setup that struck the best balance among the closeness of clusters and their separation. This configuration was ultimately chosen as the best clustering solution [73].

3.3.5. Statistical analysis

This section focuses on a statistical comparison between clusters to determine if the groups generated by the final solution show notable differences regarding the study variables. The script section initially combines the fixed cluster labels with the encoded analysis frame using ID_COL, while excluding satisfaction items from testing. Since Shapiro–Wilk and Kolmogorov–Smirnov reject normality on the pooled numeric data, subsequent comparisons adopt non-parametric methods. For numeric variables, the analysis runs both the Kruskal–Wallis test and the Mann–Whitney U test, followed by Holm correction, a step-down procedure, specifically designed to control the family-wise error rate at $\alpha = 0.05$, reducing the likelihood of false-positive findings compared to the more conservative Bonferroni correction [74]. Generally, if K>2, the roles of the Kruskal–Wallis and Mann–Whitney U (with correction) tests diverge, because the former provides a one-vs-all comparison, while the latter performs pairwise comparisons across cluster pairs. It should be acknowledged that, in the present analysis, a certain degree of methodological redundancy is inherent, since K is not greater than 2, but equals it. Nevertheless, both were applied deliberately as a robustness check, ensuring consistency of the statistical inference within the adopted clustering model (agglomerative with ward linkage, euclidean distance, and K = 2), as discussed in Chapter 4. On the other side, for categorical variables, the association with cluster membership is tested using Chi-square test on Cluster-Variable contingency tables. The resulting persona table aggregates, for each cluster, the median (min–max) of numeric variables and the

mode (frequency%) of categorical variables, with a final p-value column that maps the pertinent global test (Kruskal for numeric, Chi-square for categorical). Finally, when a difference on a numeric variable is significant, the higher-median cluster cell is flagged "*" and the lower "#", making the direction of the difference visible in the table. To conclude, the overall analytical procedure presented throughout this sub-chapter is summarised in the following flowchart (Figure 3.9), which provides a visual synthesis of all methodological steps, from data preparation to the final statistical comparisons.

Figure 3.9: Data analysis flowchart



Chapter 4 | Results

4.1. Questionnaire final layout

The final semi-quantitative tool reflects the results of a progressive development process that integrated insights from the systematic literature review with the unique features of the Neonatal Intensive Care Unit. As described in Chapter 3, the questionnaire was designed and refined through multiple steps to enhance its thoroughness, clarity, and alignment with the objectives of the study, particularly regarding the assessment of technological and organizational aspects of alarm management systems implemented in the NICU. The output resulted in a tool consisting of two questionnaires:

- The pre-questionnaire, which aims to assess the initial state of alarm management practices in the existing NICU.
- The post-questionnaire, which is to be used after launching the new Distributed Alarm System in the pilot study.

From a structural perspective, both questionnaires have similar organization, each composed of three sections:

- The first section, titled Anagrafica, collects demographic information about the respondents, including gender, age, educational background, marital status, and professional experience.
- The second section, denominated Gestione degli allarmi, constitutes the core of the tool and represents the area where the most significant differences between the two versions can be observed. In the pre-questionnaire, this part includes nine questions, whereas in the post-questionnaire it consists of nineteen. In addition, in the post-version, this second section is extended with a block of ten questions dedicated to the SUS, which specifically investigates the usability of the DAS, the integration and use of the new mobile devices, and the perceived effectiveness and efficiency of the escalation protocols. Table 4.1 presents the categorization of the items, included in the second sections of pre- and post-questionnaires, based on the

domains under investigation. It provides a clear view of how each question contributes to the assessment of the five areas examined (Decision making, Nurse stress, Work efficiency, Technologies and tools usability, and Noise level), thereby aiding in the comparison of results from the pre- and post-administration phases.

Table 4.1: Mapping of items

	Items	
Domain	**Pre-questionnaire**	**Post-questionnaire**
Decision Making	1	5 6 7
Nurse Stress	2 8 9	8 9 10 18 19
Work Efficiency	3 4	2 3 11 12 13
Technologies and tools usability	5	1 4 14 15
Noise Level	6 7	16 17

As previously discussed, all other potential domains, individuated through SLR, were excluded during the collegial revisions, as they were considered not pertinent to the specific context for which the tool is intended.

- The third section, named Esperienza di compilazione, includes four questions aimed at evaluating the respondents' impressions of the questionnaire and the project as a whole.

The final tool is presented below. The questionnaires are reported in Italian, as this is the language used for administration. The online version of the survey was developed using Google Forms, which facilitated data gathering and access for participants. Figures 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7 and 4.8 present a revised format of the original forms, to showcase the content of both the pre- and post-questionnaires.

Figure 4.1: Pre-questionnaire (1st section)

PRE-QUESTIONNAIRE

ANAGRAFICA

Genere

- M
- F

Età

- under 25
- 25-30
- 30-40
- 40-55
- over 55

Titolo di studio più elevato

- Laurea triennale o titolo equivalente
- Laurea magistrale
- Specializzazione medica e/o Dottorato di ricerca

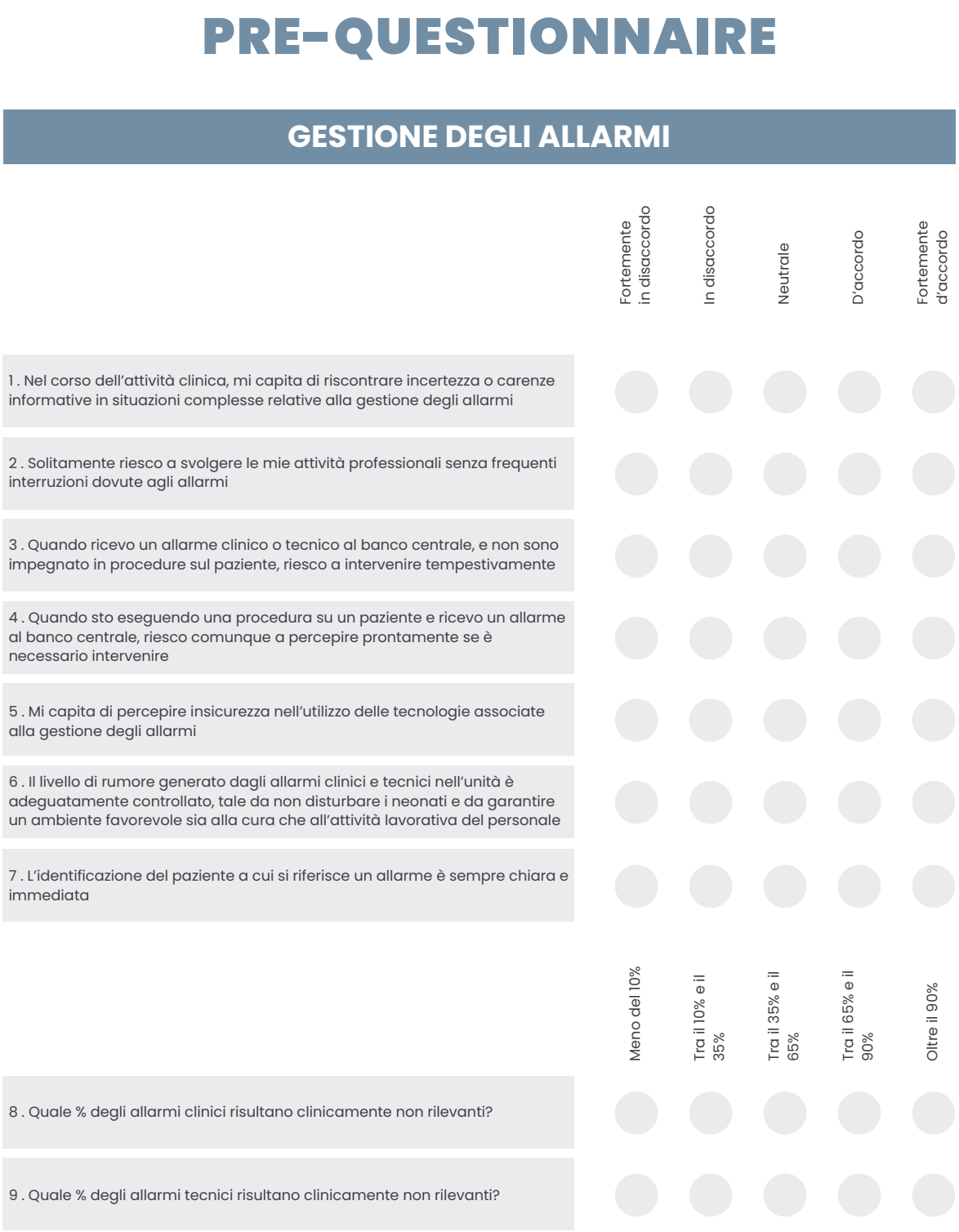
Stato civile

- Celibe/Nubile
- Coniugato/a
- Separato/a o divorziato/a
- Vedovo/a
- Preferisco non specificarlo

Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale

- Si
- No

Figure 4.2: Pre-questionnaire (2nd section)



PRE-QUESTIONNAIRE

GESTIONE DEGLI ALLARMI

	Fortemente in disaccordo	In disaccordo	Neutrale	D'accordo	Fortemente d'accordo
1 . Nel corso dell'attività clinica, mi capita di riscontrare incertezza o carenze informative in situazioni complesse relative alla gestione degli allarmi					
2 . Solitamente riesco a svolgere le mie attività professionali senza frequenti interruzioni dovute agli allarmi					
3 . Quando ricevo un allarme clinico o tecnico al banco centrale, e non sono impegnato in procedure sul paziente, riesco a intervenire tempestivamente					
4 . Quando sto eseguendo una procedura su un paziente e ricevo un allarme al banco centrale, riesco comunque a percepire prontamente se è necessario intervenire					
5 . Mi capita di percepire insicurezza nell'utilizzo delle tecnologie associate alla gestione degli allarmi					
6 . Il livello di rumore generato dagli allarmi clinici e tecnici nell'unità è adeguatamente controllato, tale da non disturbare i neonati e da garantire un ambiente favorevole sia alla cura che all'attività lavorativa del personale					
7 . L'identificazione del paziente a cui si riferisce un allarme è sempre chiara e immediata					

	Meno del 10%	Tra il 10% e il 35%	Tra il 35% e il 65%	Tra il 65% e il 90%	Oltre il 90%
8 . Quale % degli allarmi clinici risultano clinicamente non rilevanti?					
9 . Quale % degli allarmi tecnici risultano clinicamente non rilevanti?					

Figure 4.3: Pre-questionnaire (3rd section)

PRE-QUESTIONNAIRE

ESPERIENZA DI COMPILAZIONE

	Fortemente in disaccordo	In disaccordo	Neutrale	D'accordo	Fortemente d'accordo
1 . Il questionario era chiaro e comprensibile nei contenuti e nella struttura					
2 . Le domande erano pertinenti rispetto alla mia esperienza					
3 . Il tempo richiesto per completare il questionario è stato compatibile con la routine di reparto					
4 . Ritengo che strumenti come questo possano contribuire a progettare interventi di miglioramento nella pratica clinica					

Figure 4.4: Post-questionnaire (1st section)

POST-QUESTIONNAIRE

ANAGRAFICA

Genere

- M
- F

Età

- under 25
- 25-30
- 30-40
- 40-55
- over 55

Titolo di studio più elevato

- Laurea triennale o titolo equivalente
- Laurea magistrale
- Specializzazione medica e/o Dottorato di ricerca

Stato civile

- Celibe/Nubile
- Coniugato/a
- Separato/a o divorziato/a
- Vedovo/a
- Preferisco non specificarlo

Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale

- Si
- No

Figure 4.5: Post-questionnaire (2nd section, part 1)

POST-QUESTIONNAIRE

GESTIONE DEGLI ALLARMI

	Fortemente in disaccordo	In disaccordo	Neutrale	D'accordo	Fortemente d'accordo
1 . L'interfaccia di CareAssist consente di comunicare in modo chiaro la gravità della situazione clinica, ad esempio attraverso il tipo di allarme, i valori e le note					
2 . Ricevo una risposta in tempi adeguati dal medico di guardia a seguito di un'escalation					
3 . Dopo l'attivazione della modalità OCCUPATO o della delega formale, gli allarmi dei miei pazienti vengono solitamente presi in carico dal collega, se disponibile					
4 . Ricevo conferma che un allarme delegato è stato preso in carico dal collega					
5 . Se ricevo un allarme clinico sul monitor in box o su CareAssist, riesco a valutarne immediatamente la gravità senza interrompere le procedure in corso					
6 . Gli allarmi tecnici ricevuti tramite CareAssist o banco centrale sono sempre comprensibili e chiaramente associabili al dispositivo coinvolto					
7 . Sento di avere sempre un accesso rapido e chiaro alle informazioni cliniche necessarie, tramite CareAssist, centrale o monitor, per decidere come rispondere a un allarme					
8 . Se non riesco a rispondere personalmente a un allarme, percepisco comunque un senso di urgenza o pressione mentale, anche sapendo che l'allarme è visibile e acustico alla centrale					
9 . All'aumentare della frequenza degli allarmi in un breve arco di tempo (5–60 minuti), percepisco una riduzione della mia prontezza nella risposta					
10 . La possibilità di consultare parametri e allarmi di altri pazienti tramite la funzione Bed-to-Bed, dal monitor in box, contribuisce a ridurre l'impatto percepito dell'alarm fatigue					
11 . Quando ricevo un allarme clinico (da monitor o ventilatore) su CareAssist o al banco centrale, e non sono impegnato in procedure sul paziente, riesco a intervenire immediatamente					
12 . Quando sto eseguendo una procedura su un paziente e ricevo un allarme visivo (senza suono) sul monitor in box o sul ventilatore, riesco comunque a percepire prontamente se è necessario intervenire					

Figure 4.6: Post-questionnaire (2nd section, part 2)

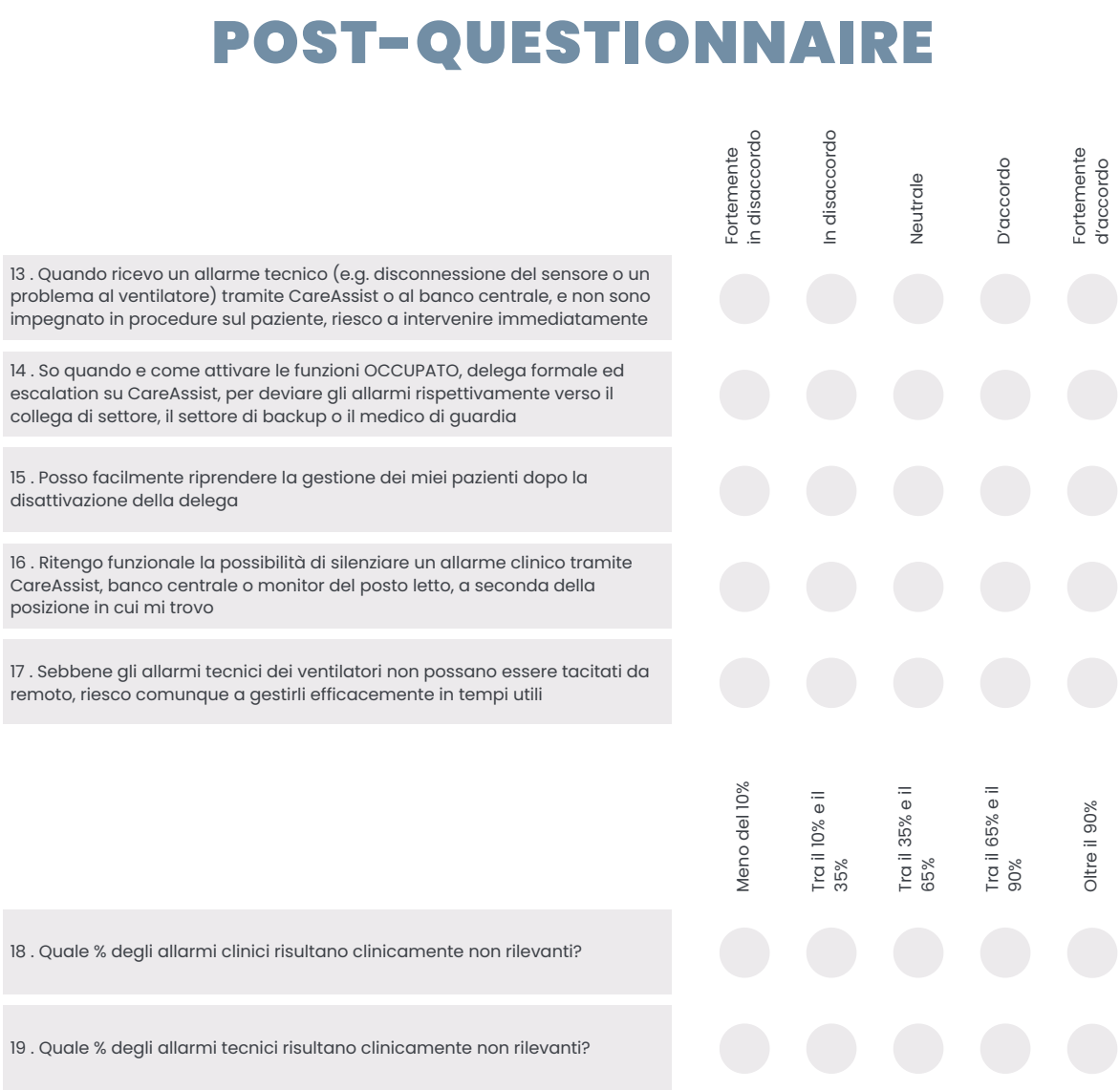


Figure 4.7: Post-questionnaire (2nd section, SUS)

POST-QUESTIONNAIRE

SYSTEM USABILITY SCALE

	Fortemente in disaccordo	In disaccordo	Neutrale	D'accordo	Fortemente d'accordo
1 . Sono favorevole a un utilizzo frequente di questo sistema					
2 . Ritengo che il sistema presenti una complessità non necessaria in alcune delle sue funzioni					
3 . Nel complesso, ho trovato il sistema facile da utilizzare					
4 . Ritengo di aver bisogno del supporto di un tecnico per utilizzare correttamente tutte le funzionalità del sistema					
5 . Le diverse componenti del sistema (CareAssist, banco centrale, monitor) risultano ben integrate tra loro					
6 . Durante l'utilizzo, ho riscontrato un'eccessiva incoerenza tra le diverse funzioni o interfacce del sistema					
7 . Ritengo che la maggior parte dei miei colleghi imparerebbe a utilizzare questo sistema in tempi rapidi					
8 . Ho trovato il sistema macchinoso o poco pratico da utilizzare nella gestione quotidiana					
9 . Mi sono sentito/a sicuro/a nell'utilizzo del sistema anche in condizioni operative complesse					
10 . Ho dovuto acquisire numerose conoscenze prima di poter utilizzare il sistema in modo efficace					

Figure 4.8: Post-questionnaire (3rd section)

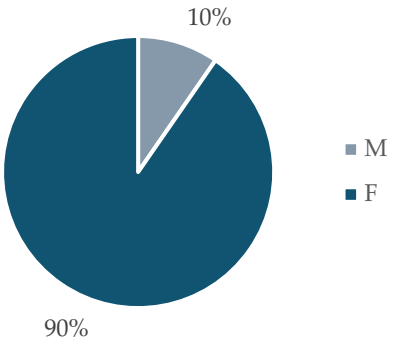
4.2. Findings from the pre-administration phase

At the current stage of the pilot study, only the pre-questionnaire has been distributed, since the project is still in its initial phase, which comes before the system update and the following post-administration phases. This section, therefore, presents and discusses only the results obtained from the initial data collection, which was carried out to create a baseline reference for the current setup of the Neonatal Intensive Care Unit. The online management of the tool was conducted using Google Forms, a platform that enabled effective distribution among the NICU staff and facilitated the automatic collection and arrangement of responses into a structured dataset. In accordance with the indications provided by the institutional Data Protection Officer (DPO), the following section reports and comments on the results of this data collection phase in aggregated form only, ensuring full compliance with privacy and ethical standards. The discussion is divided into three paragraphs, each corresponding to a section of the questionnaire: Anagrafica, Gestione degli allarmi, Esperienza di compilazione.

4.2.1. "Anagrafica"

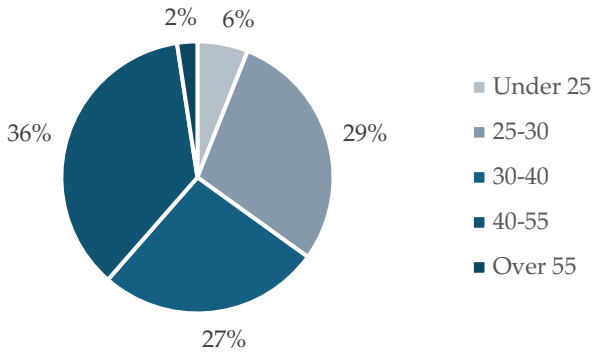
The first section comprises five questions, whose responses are discussed below. For each question, the aggregated results are presented in a pie chart accompanied by a legend, followed by a brief commentary highlighting the main findings.

Figure 4.9: Gender composition of respondents



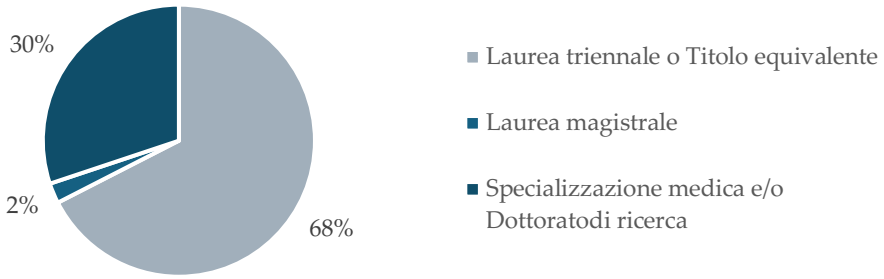
The respondents are almost entirely female (90%), with male participants representing only 10% of the total. This imbalance mirrors the gender distribution that characterizes clinicians in NICU environments, where nursing and clinical roles are predominantly held by women [75].

Figure 4.10: Age distribution of respondents



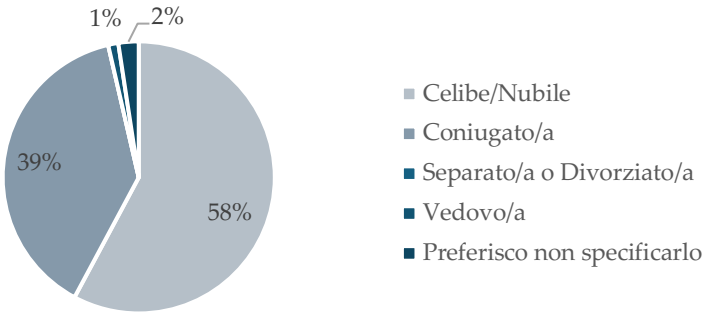
The age distribution of participants shows a balanced representation across the main professional age ranges. The largest group falls within the 40–55 years bracket (36%), followed by those aged 25–30 years (29%) and 30–40 years (27%). Younger professionals under 25 years represent 6%, while only 2% of respondents are over 55 years. This composition suggests a workforce characterized by consolidated professional experience, yet supported by a significant presence of younger staff, indicative of ongoing generational turnover within the NICU team.

Figure 4.11: Educational background of respondents



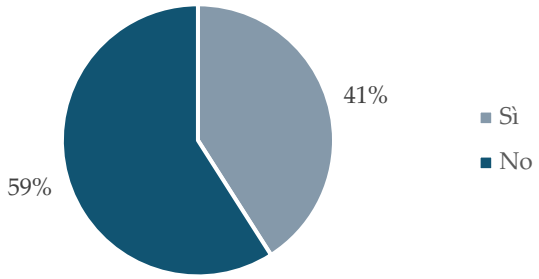
Most participants are nurses with a Bachelor's degree (68%), along with an additional 2% who hold a Master's degree, while 30% are physicians with a medical specialization. This distribution aligns with the expected academic profile of NICU professionals, primarily composed of nurses and, to a lesser extent, physicians involved in neonatal intensive care activities. Such a composition reflects the multidisciplinary nature of NICU teams, where nurses play a central role in bedside patient care and daily clinical management, while physicians contribute through diagnostic and therapeutic responsibilities [76].

Figure 4.12: Marital status of respondents



The majority of respondents reported being single (58%), followed by a considerable proportion who were married (39%). A small minority preferred not to specify their marital status (2%) or reported being widowed (1%).

Figure 4.13: Previous work experience of respondents

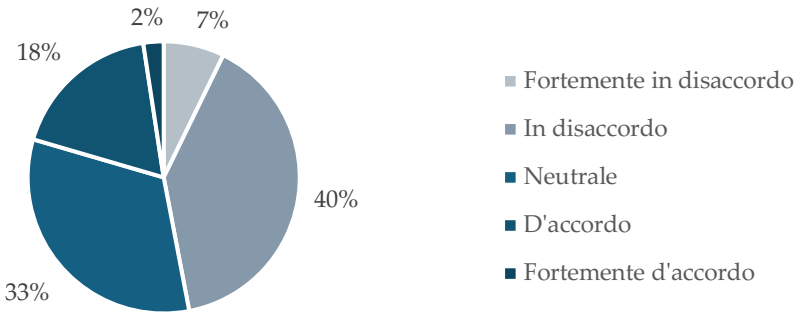


Most participants (59%) stated that they had no prior work experience in other Intensive Care Units, whereas 41% noted that they had such experience before their current position. This distribution indicates that the sample consists of experienced professionals familiar with general critical care settings, as well as personnel who have solely worked in the NICU as their only setting for intensive care. This balance helps create a varied experience, which is valuable for assessing views on alarm management.

4.2.2. "Gestione degli allarmi"

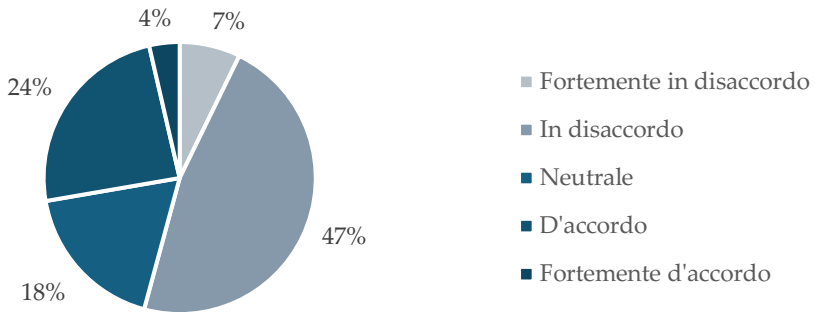
The second section comprises nine questions, whose responses are discussed below. For each question, the aggregated results are presented in a pie chart accompanied by a legend, followed by a brief commentary highlighting the main findings.

Figure 4.14: Q1 – 2nd section



This inquiry examines how professionals experience uncertainty or gaps in information that may occur in complicated clinical situations related to alarm management, evaluating the level of confidence that staff members have. The findings show that a majority of those surveyed feel quite safe in this aspect. Specifically, 40% expressed disagreement and 7% indicated strong disagreement with the statement, implying that they infrequently face scenarios involving uncertainty. At the same time, 33% of participants selected "Neutral", 18% expressed agreement and 2% expressed strong agreement. In summary, the results indicate that although most staff members feel they receive sufficient information, a significant minority still detects occasional shortcomings.

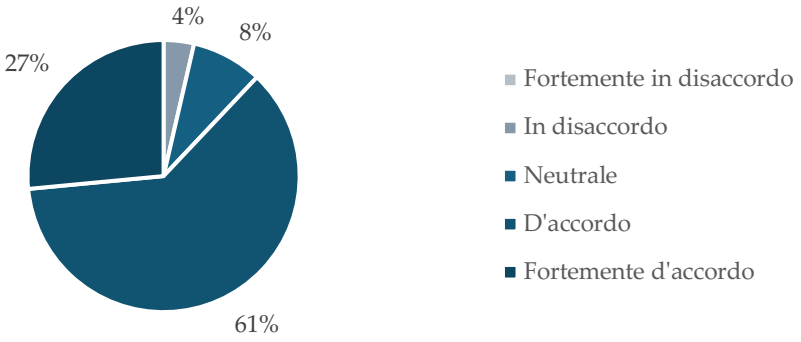
Figure 4.15: Q2 – 2nd section



The question examines how much professionals believe they can perform their clinical duties without being often disturbed by alarms. The answers show that a considerable number of participants encounter regular interruptions in their daily activities. Almost half of the individuals surveyed (47%) did not agree and 7% strongly did not agree with the statement, indicating that they frequently experience disruptions caused by alarm activations. While certain professionals

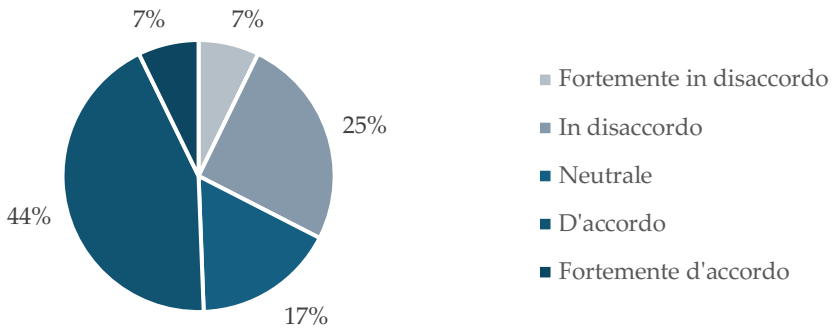
mention that the level of disruption is acceptable, most indicate that alarms continue to be a significant source of workflow interruptions. This highlights the necessity of adopting optimization strategies to minimize alerts and enhance the flow of tasks.

Figure 4.16: Q3 – 2nd section



The question pertains to the capability to quickly react to clinical or technical alarms that are received at the central monitoring station, particularly when they are not directly involved in patient care activities, to evaluate how responsive and efficient the management of alarms is under normal operating conditions. The findings indicate a distinctly favorable trend. The large majority of participants (61%) agreed, while 27% strongly agreed with the statement, suggesting that they typically succeed in responding quickly. Because only 12% reported disagreement, employees show a strong ability to respond quickly, demonstrating strong situational awareness.

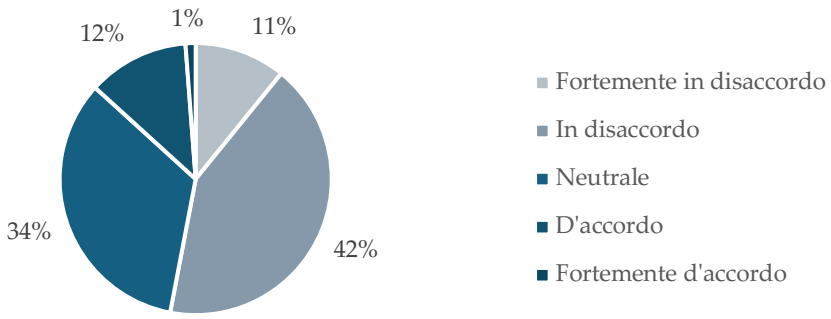
Figure 4.17: Q4 – 2nd section



The question examines the staff's awareness of their surroundings and their capability to remain focused on alarms, even while engaged in direct clinical tasks. A significant percentage of participants (44%) expressed agreement and 7% strongly

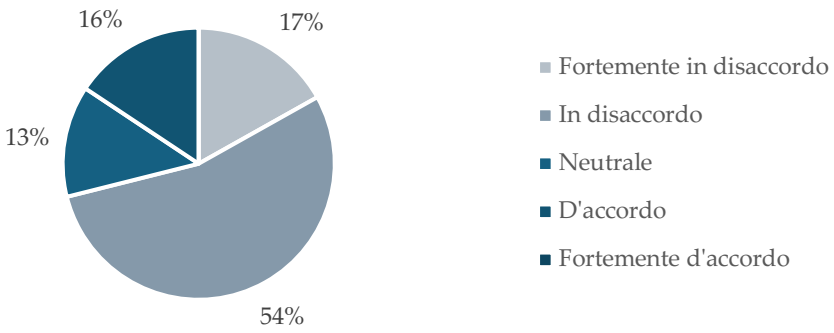
concurred with the statement, indicating that most professionals believe they can quickly determine the urgency of alarms while providing patient care. Nevertheless, 25% of participants disagreed, and 7% strongly disagreed, while 17% remained neutral. Therefore, a significant number of staff face challenges in handling both clinical duties and alarm-related responsibilities within this technological and organizational environment.

Figure 4.18: Q5 – 2nd section



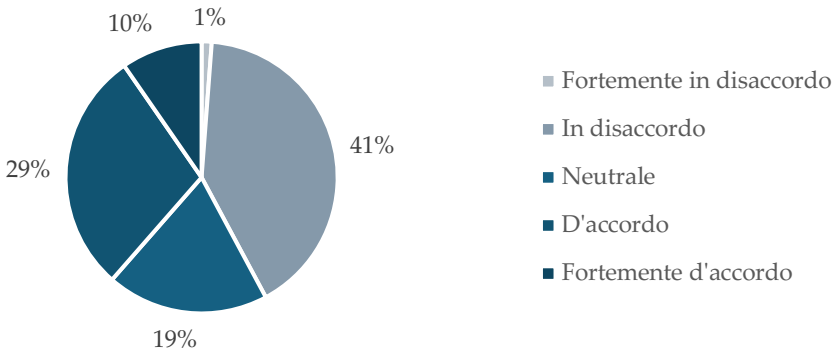
The inquiry examines the level of insecurity when utilizing technologies for alarm management. The majority of participants express confidence and security when utilizing these technologies. Indeed, 42% of the participants expressed disagreement, while 11% indicated strong disagreement with the statement, implying that they typically do not feel insecure. 34% of those surveyed maintained a neutral viewpoint, while 12% agreed, recognizing some challenges in effectively utilizing the devices. However, the information shows that most professionals possess advanced technological skills, probably because of frequent practice, a small subgroup expresses occasional uncertainty, highlighting the necessity for technological improvements.

Figure 4.19: Q6 – 2nd section



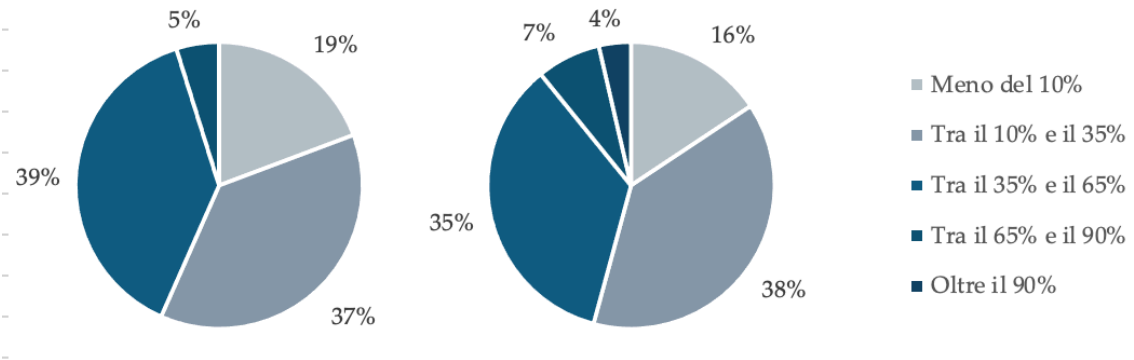
The item evaluates whether these noise levels are sufficiently managed to create a positive environment for both patient care and staff duties. Over half of the participants (54%) expressed disagreement, while 17% strongly opposed the statement, indicating that the noise from alarms is frequently too loud and could lead to alarm fatigue. In general, the results show a common belief that the existing setup of the unit does not provide adequate noise control, stressing the necessity for specific strategies designed to improve alarm sound management in order to create a quieter and safer setting for both newborns and clinicians.

Figure 4.20: Q7 – 2nd section



The inquiry seeks to assess the professionals' viewpoint regarding the recognition of the patient associated to an alarm, which is a vital element for guaranteeing timely intervention. A significant number of respondents (41%) did not agree, and 1% strongly disagreed with the assertion, suggesting that the patient linked to an alarm is not always easy to identify. This discovery highlights the importance of improving alarm traceability and the clarity of interfaces to facilitate quicker and more assured responses in critical care settings.

Figure 4.21: Q8 and Q9 – 2nd section

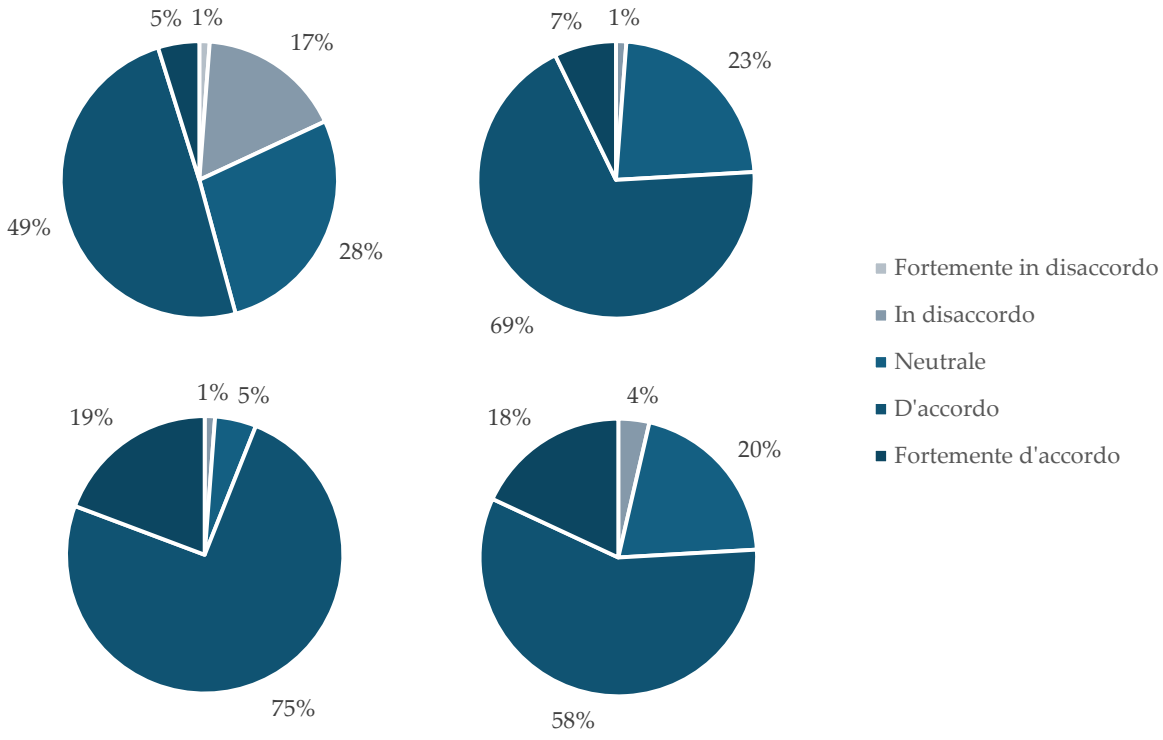


The two pie charts display the views of professionals regarding the percentage of alarms, clinical (shown in the left chart) and technical (shown in the right chart), that are considered not clinically relevant. Overall, although extreme opinions are few, the general feedback indicates a persistent worry about excessive alarm notifications. This highlights the importance of optimizing alarm configurations, improving alert prioritization, and implementing effective strategies to reduce noise, mitigating alarm fatigue.

4.2.3. "Esperienza di compilazione"

The third section comprises four questions aimed to evaluate participants' experience in completing the questionnaire.

Figure 4.22: Questions results – 3rd section



The chart located in the top-left corner pertains to evaluating if the questionnaire was clear and simple to comprehend in terms of its content and organization. The response was very favorable, with 49% of participants expressing agreement and 28% indicating strong agreement, affirming that the tool was effectively designed and easy to use. Additionally, the chart in the upper right examines if the questions were applicable to the professional experiences of the participants and the results

were largely positive: 69% of participants strongly agreed and 23% agreed, suggesting that the questionnaire was viewed as very relevant to daily clinical practices and duties. This success is believed to result from a well-structured design process that integrates evidence from the literature with the specific context of Mangiagalli's NICU. Lastly, the chart located in the bottom-left corner analyzes how well the time needed for completion aligns with the clinical routine, and the chart in the bottom right focuses on the belief that tools such as this can assist in developing better interventions for clinical practice. Most participants showed significant agreement, with 58% agreeing and 20% strongly agreeing, acknowledging the likely benefits of the questionnaire as an instrument for self-reflection and improving quality. Merely 18% expressed disagreement, and 4% strongly disagreed, suggesting that most professionals consider the whole project to be beneficial aids for enhancing both organizational and clinical performance.

4.3. Identification and characterization of user personas

In this section, the results of the data analysis are presented, leading to the identification and characterization of user personas for this first study phase. Before introducing the personas, the intermediate steps that guided the identification are discussed, as they provide essential insights into the choices made along the way. Specifically, the following subsections focus on the most relevant stages of the analysis: the EDA, the dimensionality reduction techniques, and the clustering.

EDA

The exploratory data analysis focuses on the information collected through the questionnaire, examining first the distribution of numerical variables, and then exploring the relationships among numerical variables, among categorical variables, and between numerical and categorical variables. In the initial phase, the possible presence of missing data was examined and, as illustrated in the missingness pattern (Appendix A - Figure A.1), the dataset does not exhibit any. This avoids imputation procedures or case exclusions. Once the synthetic scores were calculated, as reported in Table 4.2, univariate analysis was performed to assess their normality.

Table 4.2: Synthetic scores explanation

Score	Meaning
Score_1	Perception of informative uncertainty[7] in alarm management (higher values indicate lower uncertainty).
Score_2	Ability to maintain operational continuity despite interruptions caused by alarms.
Score_3	Responsiveness to intervene and ability to detect alarm during clinical procedures.
Score_4	Perceived uncertainty in using technologies (higher values indicate lower uncertainty).
Score_5	Evaluation of the acoustic environment and clarity in identifying patients.

[7] Informational uncertainty describes a condition in which available information is insufficient to clearly interpret the clinical context and identify the nature of the alarm. As a result, operators may experience uncertainty in choosing the appropriate procedure to manage the alarm, not due to lack of competence necessarily, but because the situation is not yet sufficiently defined to determine the correct course of action. It is noted that the action to be taken to manage alarms depends on the operator's role, and consequently, different roles require different types of information to make role-appropriate decisions.

The results of the Shapiro-Wilk normality test (Appendix B – Table B.1), indicate that none of the numerical variables follow a normal distribution ($p < 0.05$ for all scores), a finding graphically confirmed by Figure A.2 in Appendix A. This evidence supports the use of non-parametric methods for subsequent bivariate analyses, such as Spearman's correlation and the Kruskal-Wallis test. The result of the former (Appendix A - Figure A.3) presents a moderate positive correlation between Score_1 and Score_4 ($\varrho = 0.65$), indicating that greater perceived confidence in using technologies is linked to reduced informational uncertainty in managing alerts, indicating that the perception of technological competence contributes to the feelings of control and operational clarity. Additionally, a moderate correlation exists between Score_2 and Score_5 ($\varrho = 0.43$), indicating that the ability to manage operational interruptions is positively related to the perception of an acoustically suitable work environment. Finally, weaker but consistent relationships are observed between Score_3 and Score_5 ($\varrho = 0.38$), indicating that the readiness to intervene is enhanced in an environment where noise levels are managed effectively. None of the correlations exceed 0.80, thereby excluding issues of multicollinearity and informational redundancy among the numerical indicators. Regarding the relationships between categorical variables, Cramér's V matrix (Appendix A - Figure A.4) reveals mostly weak associations, consistent with the independent nature of the socio-demographic characteristics of the sample. The most notable association is observed between age and educational attainment ($V = 0.44$), explained by the fact that the nursing degree, being shorter in duration, allows nurses to start working at a younger age, whereas physicians, who complete longer specialization programs, are generally over 40, with only a few around 35. A moderate link exists also between educational qualifications and work experience in different ICUs ($V = 0.42$), because physicians, classified in the last level of education, generally have accrued professional experience in non-neonatal intensive care environments. Other associations, such as the one between gender and age ($V = 0.23$) or between marital status and age ($V = 0.36$), remain weak and lack structural significance. Finally, the relationships between numerical and categorical variables were examined using the Kruskal–Wallis test (Appendix B – Table B.2). The analysis revealed that Score_2 shows statistically significant differences based on gender ($p = 0.0049$), suggesting that perceptions of operational continuity may vary between male and female professionals. Moreover, Score_4 differs significantly depending on work experience in other Intensive Care Units ($p = 0.0075$), indicating that professionals with broader ICU experience tend to report greater confidence in using technologies. In summary, the exploratory data analysis

confirmed the internal consistency of the data and highlighted meaningful links between operational perceptions, environmental factors, and professional characteristics, providing a description of the foundation.

DIMENSIONALITY REDUCTION TECHNIQUES

Following the exploratory data analysis, the next step involved the use of dimensionality reduction techniques aimed at summarizing the information present in the dataset and simplifying the subsequent clustering phase. PCA, as illustrated in the graph of cumulative explained variance (Figure 4.23) and confirmed by the inflection point in the scree plot (Figure 4.24), individuates six principal components to account for approximately 84% of the total variance. This result indicates a well-focused informational structure, where a limited number of linear combinations of the synthetic scores are able to capture most of the variability (>80%) present in the data.

Figure 4.23: PCA cumulative explained variance

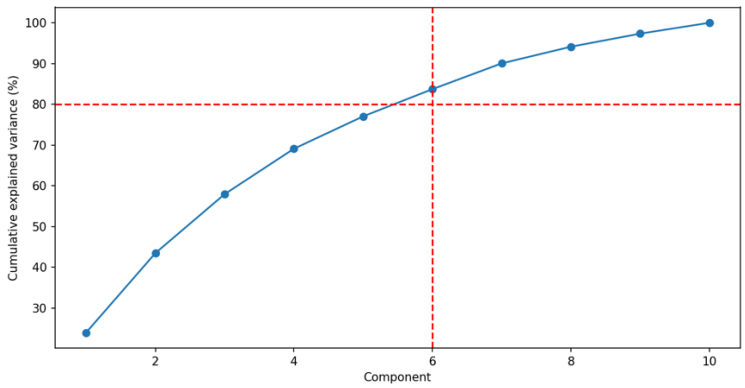
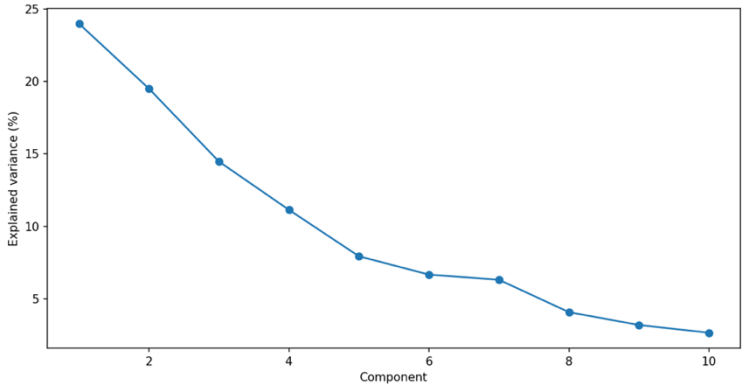


Figure 4.24: PCA scree plot



Similarly, FAMD, executed in both Python and R environments, provided cumulative variance curves indicating that the first seven components account for

approximately 81% and 85% of the total variance, respectively, as illustrated in Figure 4.25 and Figure 4.26. Finally, PCAmix, implemented in the R environment, shows six principal components account for approximately 84% of the variance (Figure 4.27).

Figure 4.25: FAMD cumulative explained variance

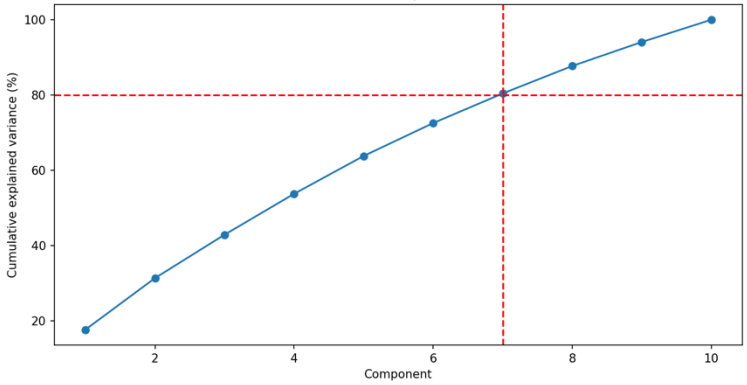


Figure 4.26: FAMD_R cumulative explained variance

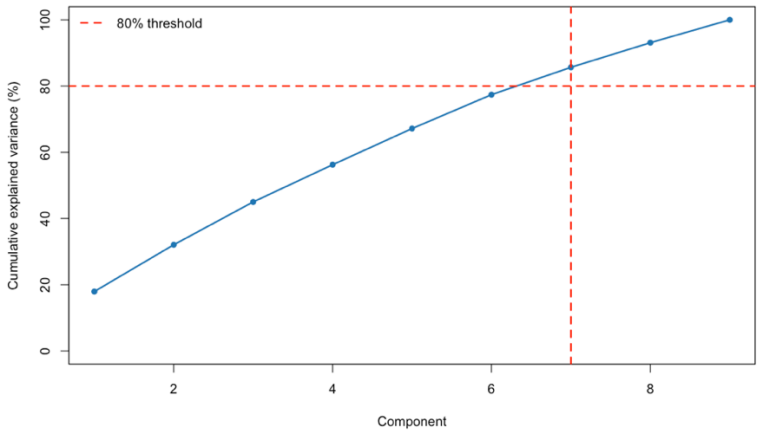
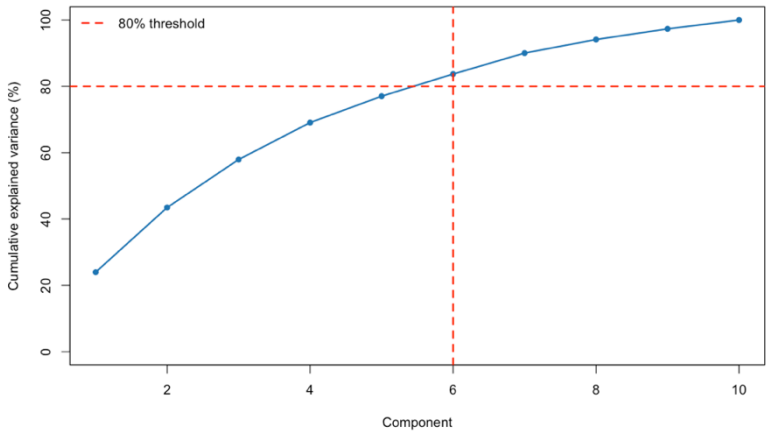


Figure 4.27: PCAmix_R cumulative explained variance



For completeness, the scree plots for the FAMD, FAMD_R, and PCAmix_R techniques are reported in Appendix A (Figure A.5, Figure A.6 and Figure A.7).

Overall, the consistency of the results achieved through these techniques indicates a significant structural stability of the data and supports the decision to choose a limited number of components (six or seven) to effectively represent the initial information.

CLUSTERING

The clustering phase was carried out using the components obtained through the several dimensionality reduction techniques, with the aim of identifying homogeneous groups of observations within the variable space. Both hierarchical agglomerative methods and partitioning methods based on K-Medoids were employed, with various linkages and metrics. The outcomes of the various configurations are presented in the graphs of Figure 4.28 (PCA), Figure 4.29 (FAMD), Figure 4.30 (FAMD_R), and Figure 4.31 (PCAmix_R).

Figure 4.28: Clustering methods - PCA

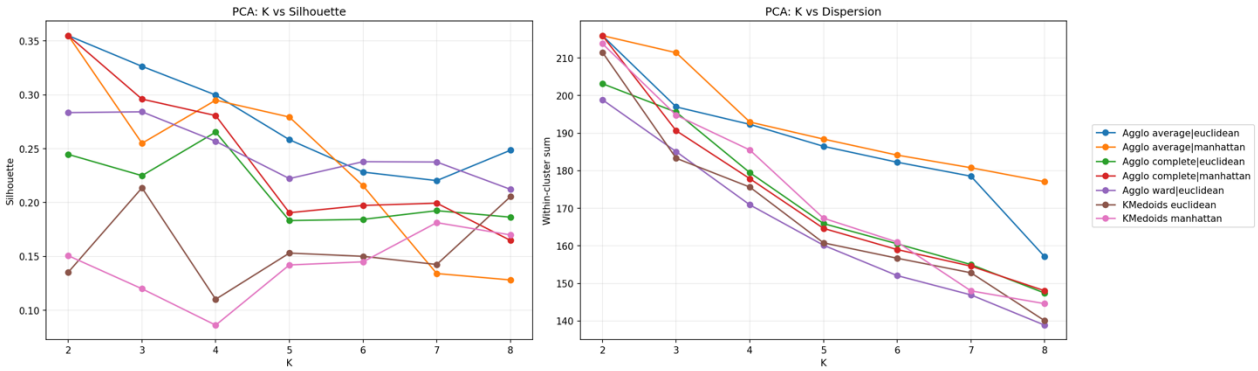


Figure 4.29: Clustering methods - FAMD

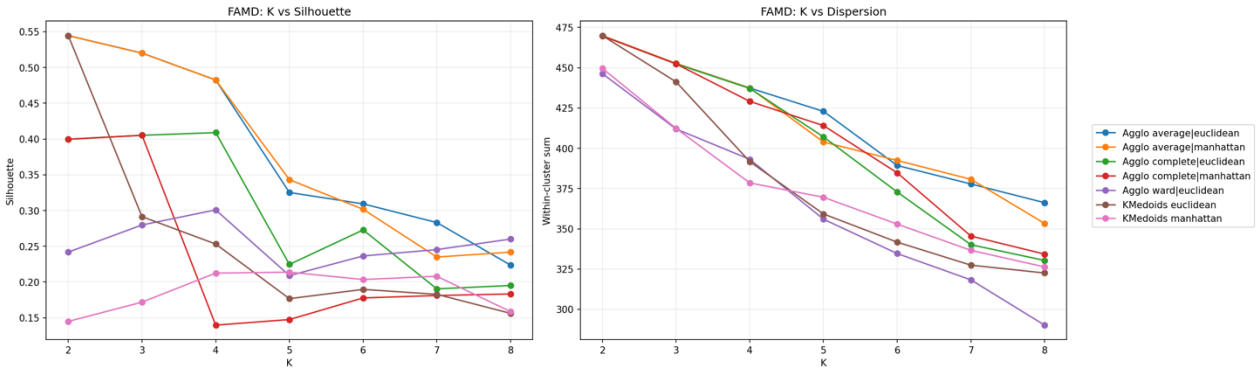


Figure 4.30: Clustering methods - FAMD_R

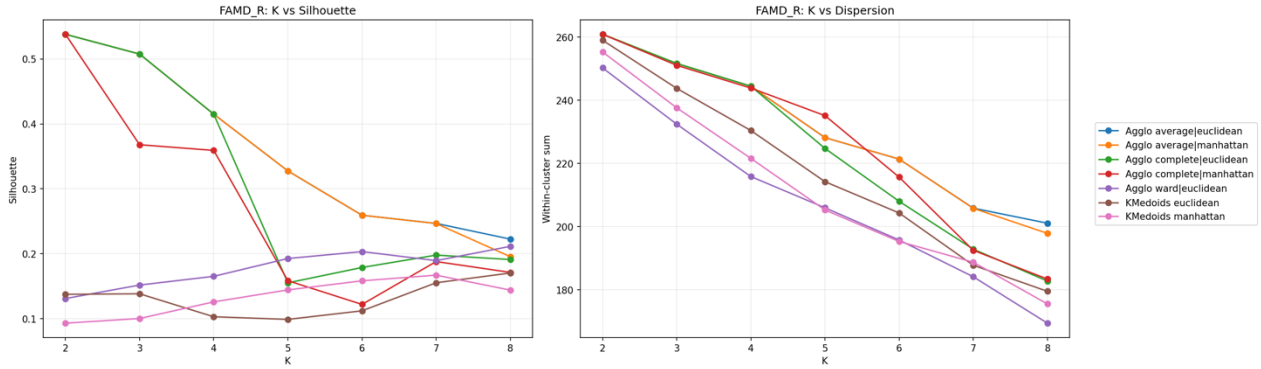
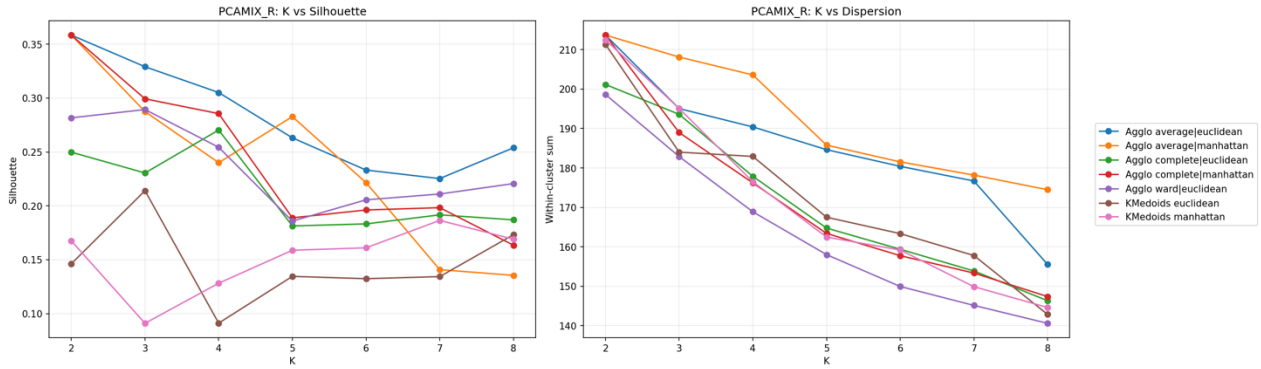


Figure 4.31: Clustering methods - PCAmix_R



These figures illustrate the trend of the silhouette index and the intra-cluster dispersion as K, linkage and metric used change. The decision-making process for identifying the optimal configuration primarily relied on the silhouette index, which evaluates the level of cohesion and separation among the clusters. Additionally, intra-cluster dispersion was used to assess the internal compactness of the partitions. From this combined analysis, it was found that the best solution is the PCAmix_R reduction clustered according to the ward agglomerative algorithm and euclidean distance, with K=2 clusters. This configuration demonstrates the best balance between internal homogeneity and external separation, highlighting a stable structure.

PERSONAS

In the realm of statistical inference, a statistically significant difference is defined as the condition in which the likelihood of obtaining a result that is equal to or more extreme than the observed one, while assuming the null hypothesis (H_0) of equality between groups to be true, is lower than the predetermined significance level, typically set at α = 0.05. In other terms, this means that if we accept the null

hypothesis as true, the likelihood of having a Type I error (reject the equality hypothesis when it is actually true) is less than 5%. If the calculated p-value is below the α, the null hypothesis is rejected, meaning that the observed difference between the groups results statistically inconsistent with the assumption of no effect. It is, however, essential to note that the lack of statistical significance does not mean that there is no difference. A non-significant result simply means that, based on the analyzed sample and the observed variability, there is not enough evidence to reject the null hypothesis with that preestablished significance level [77][78]. Given this premise, non-parametric statistical tests were conducted to identify the significant differences between the two clusters, enhancing a personas characterization supported by the statistically significant distinctions. The results of these tests are reported in Appendix B (Tables B.3, B.4 and B.5) for completeness, while Table 4.3 presents Persona Table.

Table 4.3: Persona table

	Cluster 0	**Cluster 1**	**p-value**
Cluster Size	22	61	
Score_1	2.0 (0.0-4.0)#	3.0 (0.0-4.0)*	0.004
Score_2	2.7 (1.7-3.7)*	2.3 (0.3-3.7)#	0.053
Score_3	3.0 (1.5-4.0)	2.5 (0.5-4.0)	0.400
Score_4	2.0 (0.0-4.0)#	3.0 (1.0-4.0)*	<0.001
Score_5	1.2 (0.5-2.5)	1.5 (0.5-3.5)	0.492
Genere	1 (63.6%)	1 (100.0%)	<0.001
Età	3 (54.5%)	1 (36.1%)	0.007
Titolo di studio più elevato	2 (77.3%)	0 (83.6%)	<0.001
Stato civile	1 (50.0%)	0 (65.6%)	0.008
Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale	1 (86.4%)	0 (75.4%)	<0.001

It is highlighted that clusters are characterized by significant differences in procedural choosing and technological security. Cluster 1 exhibits higher median values in Score 1 and Score 4 (3.0 compared to 2.0), which respectively reflect a clearer understanding of what actions to take (according to available information and operator's role), when an alarm is triggered and greater confidence in the use of technologies. Cluster 0, on the other hand, shows lower medians in the same areas, outlining a profile marked by slightly greater uncertainty. However, these values fall within the mid-to-positive portion of the 0-4 scale, where 2 means a

satisfactory level of proficiency and 3 represents an above-average level of proficiency. Concerning Score 2, which assesses the ability to ensure operational continuity despite interruptions caused by alarms, a slight trend difference is observed between the two clusters, with median values being slightly higher for Cluster 0 (2.7 compared to 2.3). However, the absence of statistical significance suggests that the distinction cannot be deemed structural. Score 3, which evaluates the readiness to respond to alarms, shows no statistically significant differences between clusters (3.0 for Cluster 0 and 2.5 for Cluster 1). Nevertheless, both groups report really high median values, indicating that, regardless of cluster membership, operators demonstrate a strong ability to recognize and respond promptly to alarms, even during clinical procedures. Regarding Score 5, which indicates how noise from alarms is perceived, it reveals low and almost the same median values for both groups (1.2 for Cluster 0 and 1.5 for Cluster 1). While no statistically significant difference was found between the two groups, an important observation arises: both groups express a strong sense of excessive noise, which is further intensified by the challenge of quickly determining the patient related to the alarm. This signifies an important problem, as it may lead to alarm fatigue and could impede timely response. Additionally, categorical variables, analysed using the Chi-square test, provide further insights into the structural distinctions between the two groups, because notable distinctions arise concerning gender, age, education level, marital status, and work experience. Cluster 1 includes only female professionals, with nurses representing the vast majority (83.6%), and the most frequent age group falling between 25 and 30. Cluster 0, on the other hand, is mainly composed of medical doctors, typically aged between 40 and 55, and characterized by previous professional experience in Intensive Care Units. These characteristics indicate that the two groups do not just have different perception or attitudes; instead, they represent separate socio-professional identities within the healthcare sector. Overall, the results indicate that the identified personas do not represent a mere division of the respondents, but rather two significant and consistent clusters of the observed reality. The existence of statistically significant differences in key domains, confirms the validity of the clustering model used and enhances the descriptive strength of the derived user personas. These latter must be seen as two distinct professional archetypes that differ not only in their socio-demographic and educational characteristics but also in their perceptions interacting within NICU working environment. Figures 4.32 and 4.33 below present a reformulation of the discussed insights, structured as Persona cards of the two archetypes and providing a comprehensive depiction of their key traits, perspectives, and necessities.

Figure 4.32: Persona card - Cluster 0

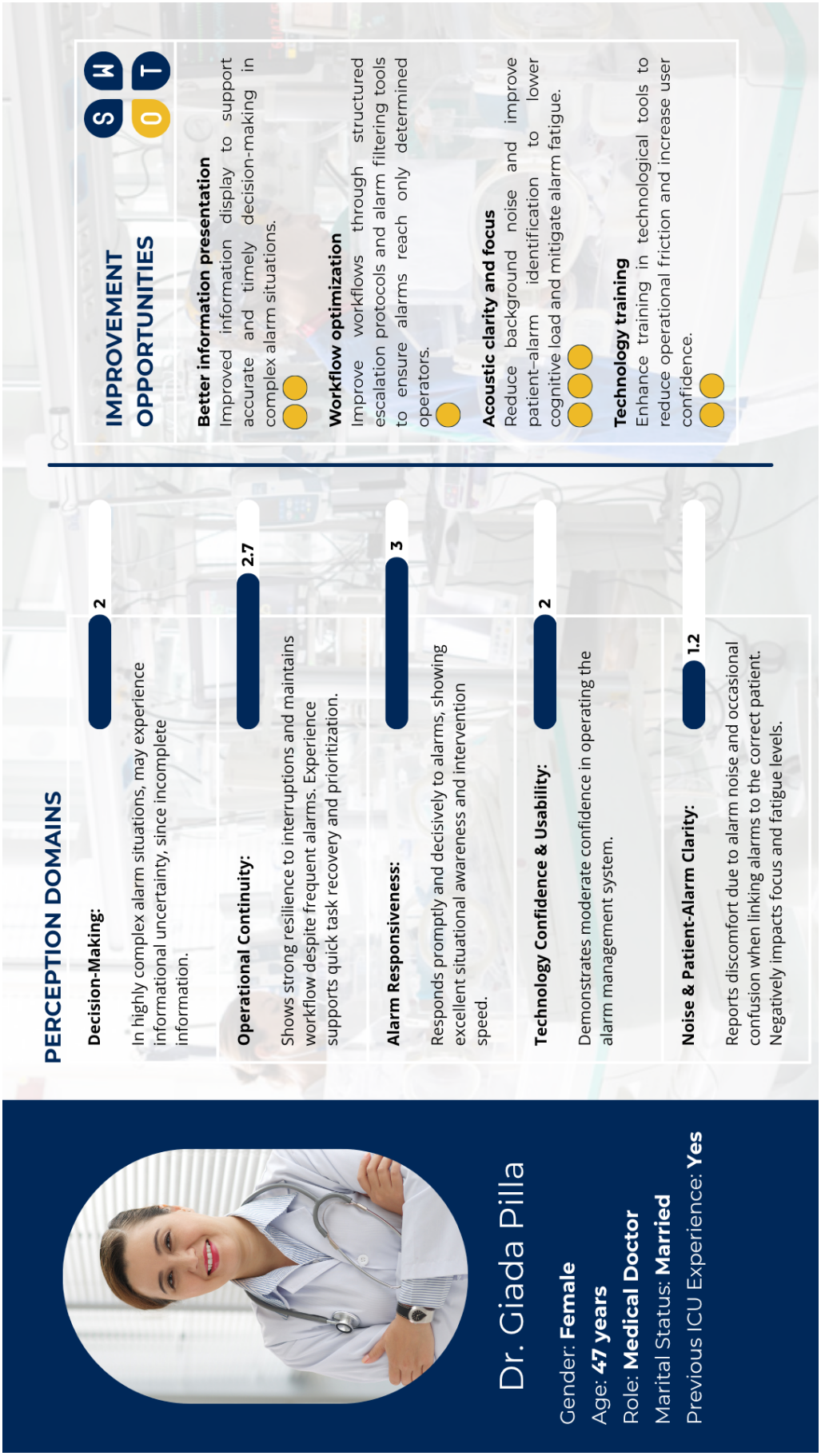
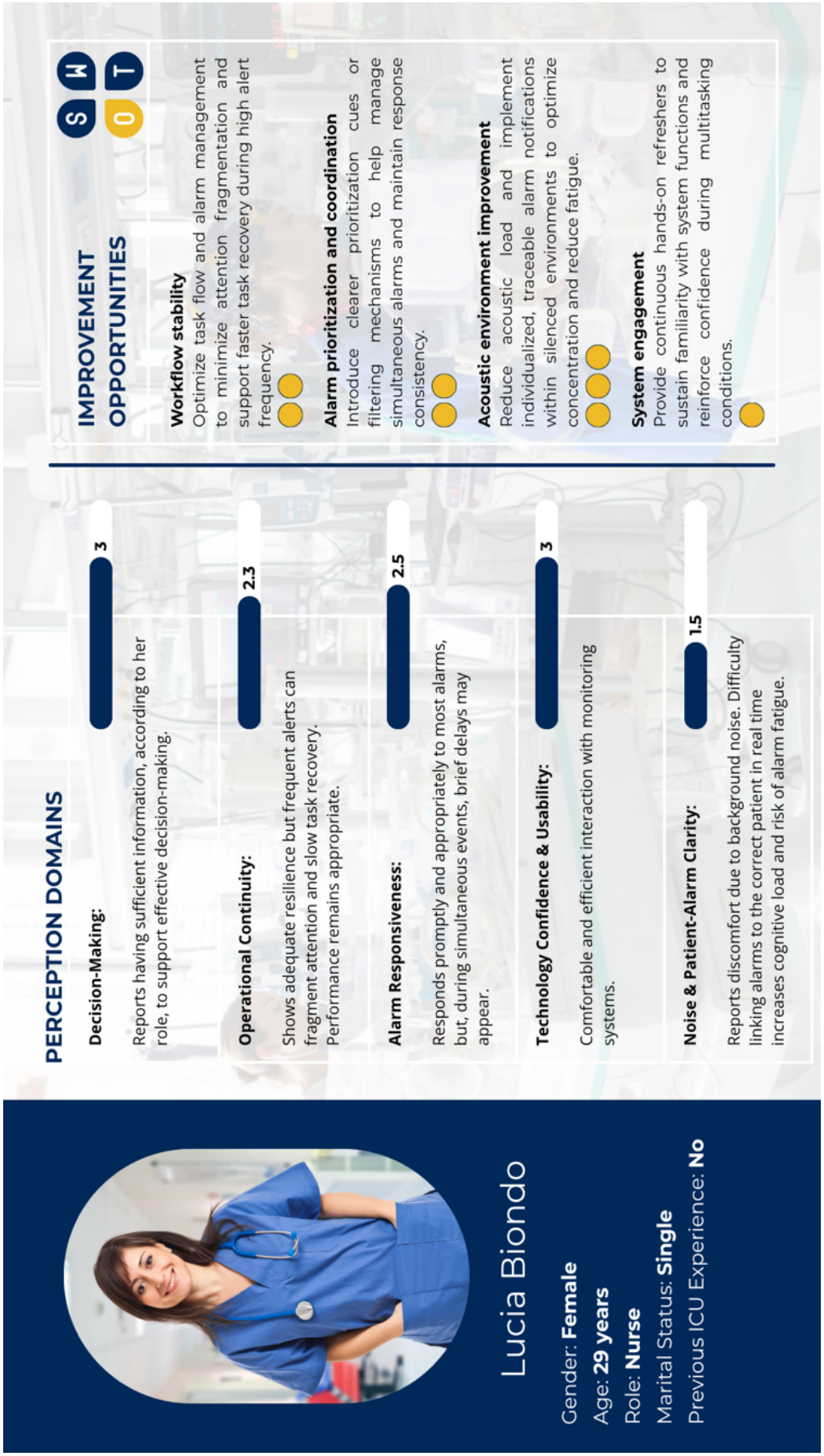


Figure 4.33: Persona card - Cluster 1



Chapter 5 | Conclusions and future developments

As has been demonstrated, the NICU is inherently a critical context: margin for error is minimal, response times must be minimized, technology adopted is not trivial, and acoustic load in the environment must be managed. In this context, transitioning to a distributed alarm management system, featuring dedicated server architecture, delegation and escalation protocols, and the introduction of Silent Rooms, represents not merely an organizational and technological upgrade, but a re-evaluation of the entire socio-technical environment that oversees safety, accountability, and continuity of care. To support this relocation, a two-phase pilot project has been specifically designed, consisting of a pre-phase, in which personnel operate within the standard configuration, and a post-phase, which simulates the post-transfer setup. This approach serves a twofold purpose: to train staff on the new operational model and to identify, prior to the relocation, any potential process or interface issues, allowing for corrective actions to be taken in advance without posing risks to patients. In other words, the tool is thought to assess in a practical setting how individuals and technology interact. To systematically measure the impact, a semi-quantitative questionnaire has been developed based on existing literature and adapted to the specific context. The "pre" version captures the current state; the "post" version, enhanced by the SUS, will reflect usability, effectiveness, and the integration of the distributed model and workflows in mobility. The parallel structure of the two versions, organized around domains such as decision-making, nursing stress, efficiency, usability of tools, and noise levels, facilitates the comparison of pilot phases and allows for a more confident attribution of changes to the technological and organizational transformation implemented. The analysis of the data collected during the "pre" phase of the pilot provides an important overview in the current state of the system-team interaction. Overall, the team exhibits a high level of readiness and a strong ability to manage alerts even during peak periods of care. What stands out as a critical point, perfectly aligning the reality of the Clinica Mangiagalli with literature, is not the management of the event itself, but rather the acoustic environment and the speed with which each alarm can be distinctly linked to the correct patient. In an organizational model consisting of

distributed sectors composed of Silent Rooms, where sound has been relocated outside the patient box to the sector hub, these issues are expected to progressively decrease, since alarms will sound only at the sector hub and not inside the newborn's silenced box. Furthermore, this disruptive design is anticipated to facilitate the identification of the patient linked to each alarm, as each operator will receive alerts only for the three patients assigned to them during regular, non-delegated working situations. In this manner, when compared to the typical setup, operators would oversee fewer beds, facilitating the process of identifying patients, an improvement also supported by the fact that each designated box corresponds to one specific patient, contrasting sharply with the arrangement found in an open-bay design. More specifically, two well-defined professional personas, representing real archetypes of the users of the current alarm management system, emerge. A particularly significant aspect of the first persona pertains to the prioritization and coordination of alarms, as their reception in open-bay environments tends to disrupt the continuity of care when assistance is already being provided to another patient, because in such situations, the overlap of simultaneous signals can scatter attention of the operator. The establishment of clearer mechanisms for prioritizing or filtering alerts could assist in better managing these situations, ensuring greater consistency in actions and minimizing cognitive interference. It is reasonable to suggest that the implementation of a distributed model could greatly lessen this vulnerability. The decrease in acoustic noise, enabled by the distribution of centers and the isolation into sectors, will indeed promote a quieter and more focused environment, reducing sensory distractions and enhancing the ability to restore concentration during caregiving activities. Differently, the second profile highlights, a concern related to the presentation of information in complex alarm situations. The fragmentation of clinical data and its distribution across multiple interfaces often slows down the decision-making process, creating a level of informational uncertainty that is particularly characteristic of this type of user, which predominantly reflects the role of the physician. This difference is consistent with the distinction between the roles of physicians and nurses, as well as the different types of actions required in response to specific alarms. From this, the need arises to enhance the clarity and completeness of the information presented by the system, for instance, through more integrated and structured displays based on clinical priorities, allowing for a more immediate and coherent understanding of the context. It is hoped that these features will distinguish the new alarm management system, making data consultation smoother and reducing decision-making uncertainty. Another distinctive feature of this profile pertains to the confidence in

the use of technology. By demonstrating expertise and control, this type of user tends to approach innovation cautiously. In this perspective, the pilot plays a crucial role as it serves as a regulated opportunity to test the new system, strengthen familiarity with its features, and encourage a gradual learning process. For this user, training in a simulated or semi-real environment is not only educational but also protective, as it helps build confidence in using new technologies without the risk of encountering challenges when the department transitions to the new location. Concluding, the recognition of these two personas during the pre-analysis creates an essential foundation, a clear reference point that accurately reflects the current practice within the examined NICU setting. In addition to verifying the strengths of the team, this phase also emphasizes both the common and individual weaknesses of the users. Weaknesses not only reflect the well-established information found in the literature regarding open-bay layouts but also outline the particular areas where improvements can realistically be expected with the implementation of the new system. Building on this foundation, the future development of the project will be guided by the management and evaluation of the post-phase, which can be implemented only after the software release upgrade, to ascertain whether the identified vulnerabilities have been successfully addressed or if new ones have arisen, eventually facilitating their prompt resolution prior to moving to the new building. In this manner, the pilot functions not only as a training tool but also as a systematic method for verification and improvement: a protective measure that guarantees the shift to the new environment takes place with a comprehensive understanding of the system's human and technical elements. Only in this way, the move will not represent a step into uncertainty but rather a gradual, data-driven, and carefully evaluated process aimed at improving safety, concentration, and well-being for infants and healthcare personnel.

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Appendix A

Figure A.1: Missingness map

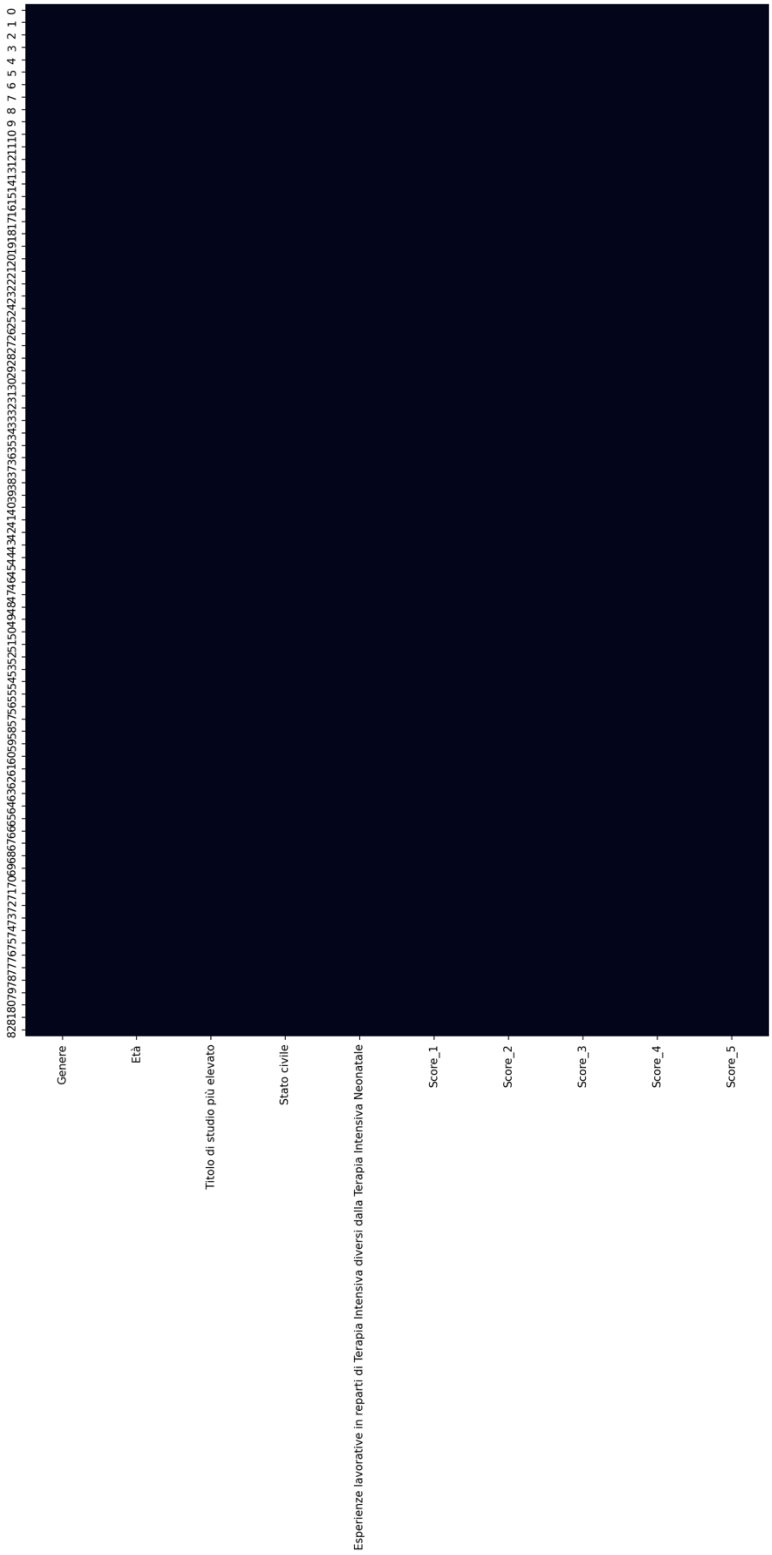


Figure A.2: Synthetic scores distribution

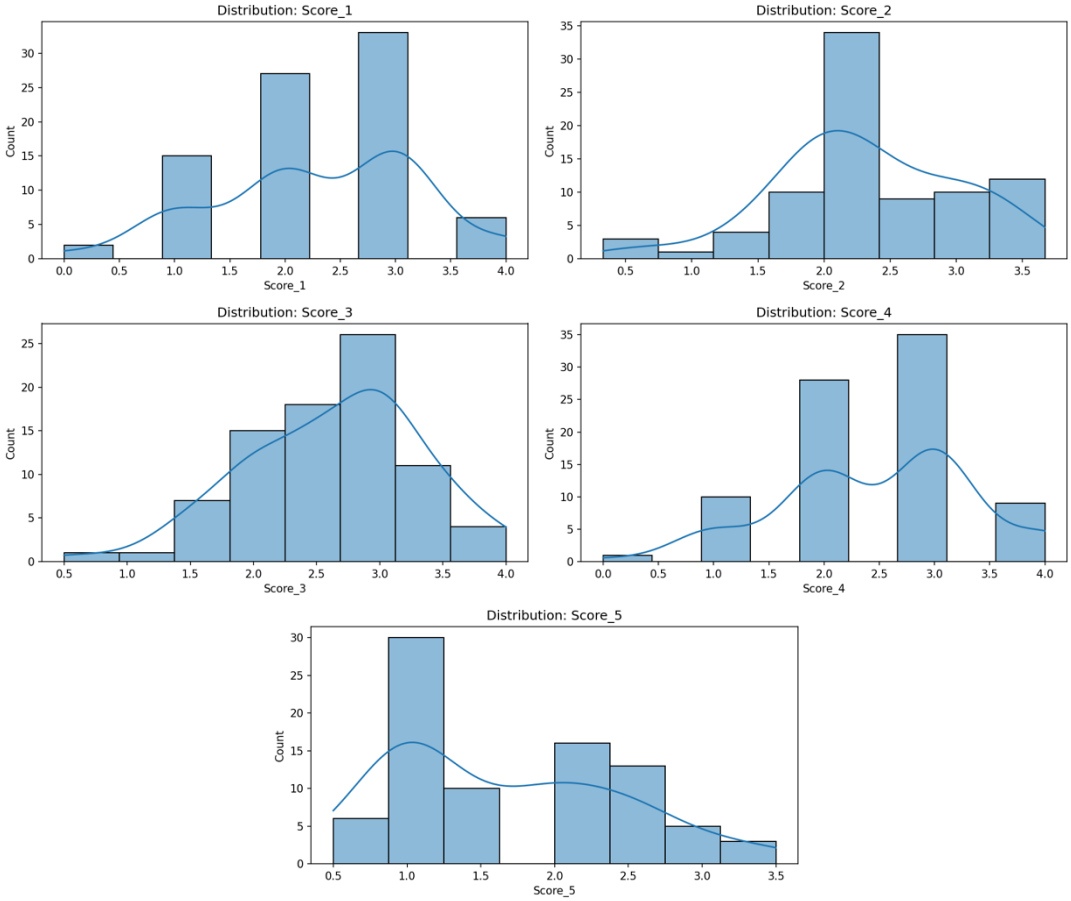


Figure A.3: Spearman heatmap

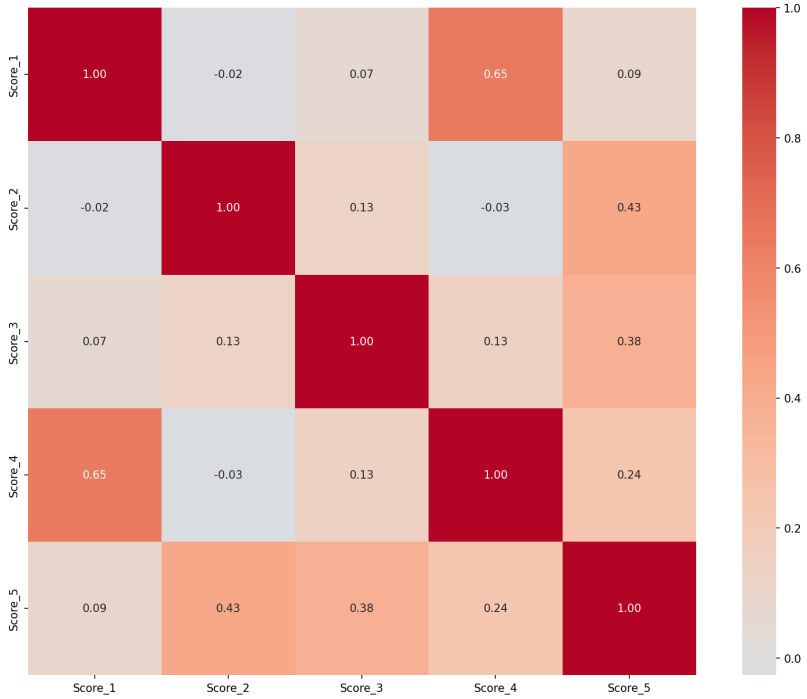


Figure A.4: Cramér's V heatmap

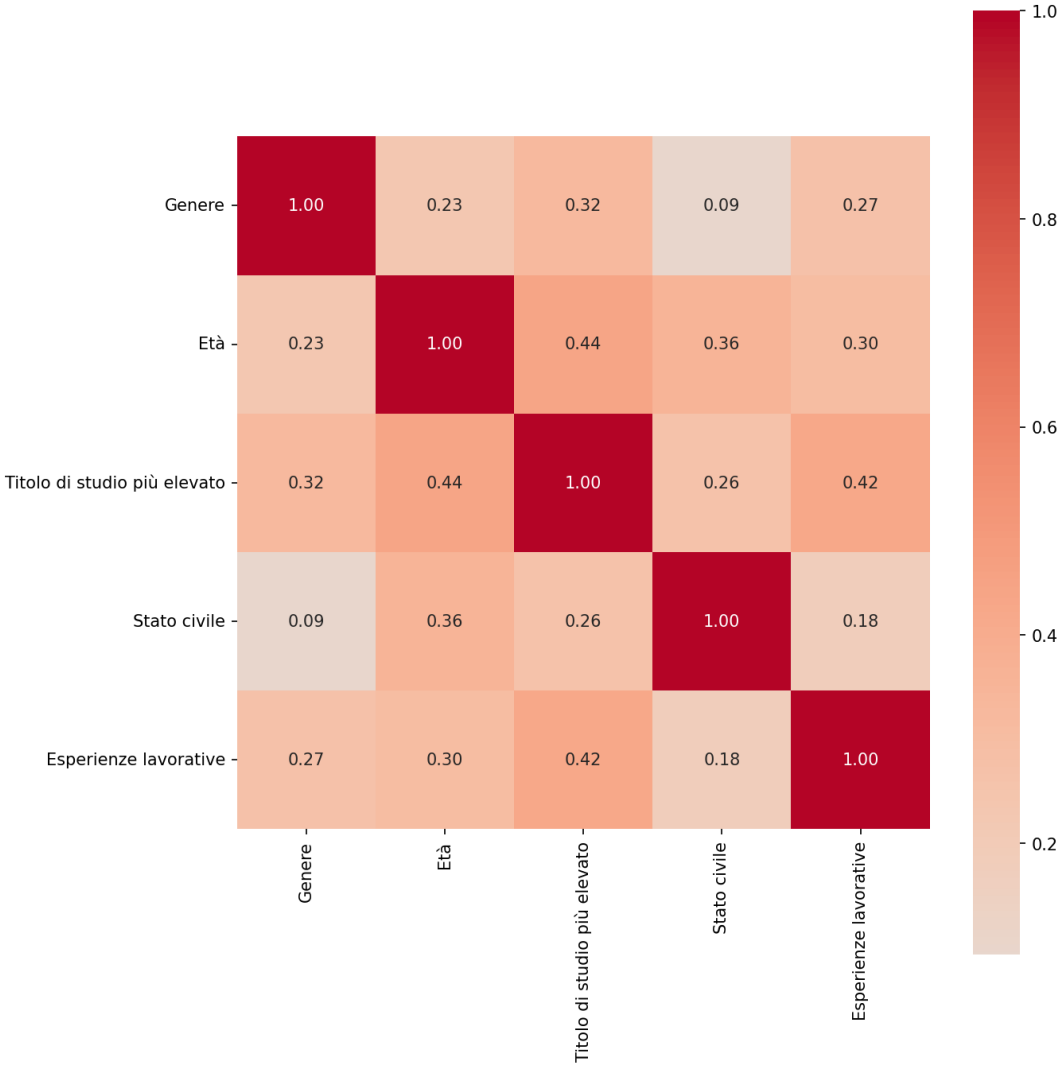


Figure A.5: FAMD scree plot

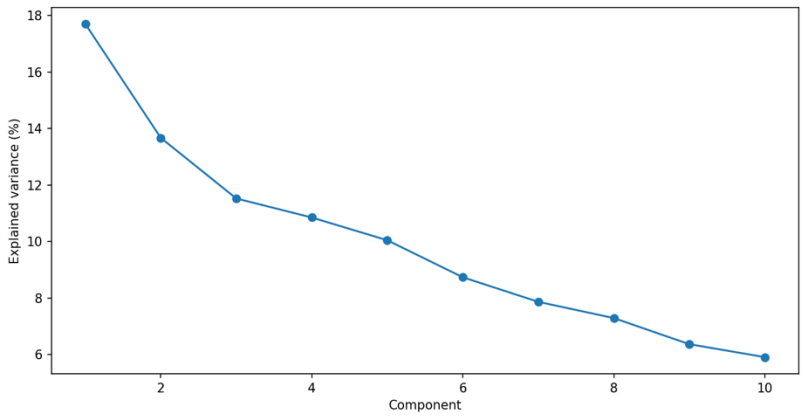


Figure A.6: FAMD_R scree plot

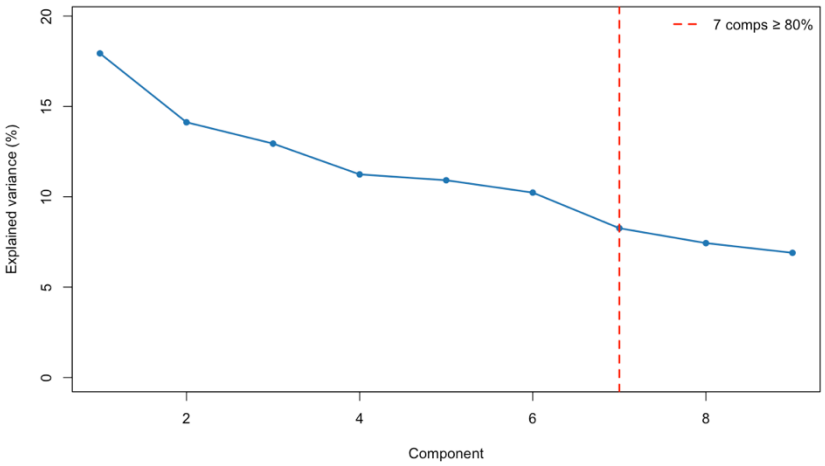
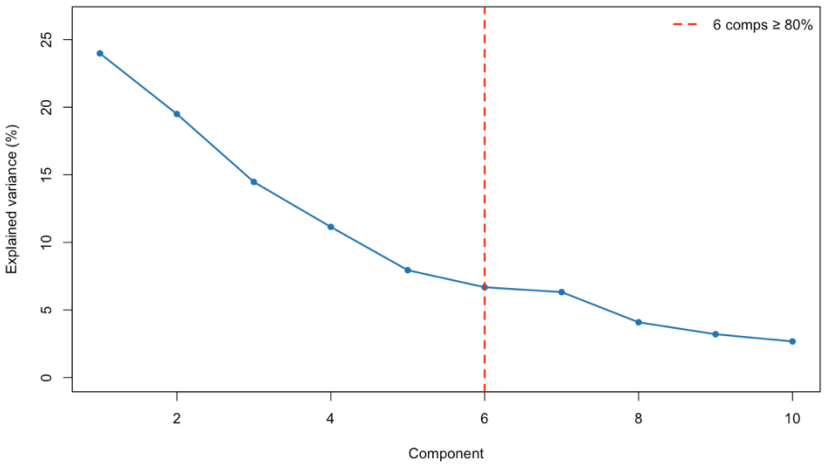


Figure A.7: PCAmix_R scree plot



Appendix B

Table B.1: Shapiro-Wilk test results (EDA)

Variable	W statistic	p-value	Normal
Score_1	0.8882	2.81×10^{-6}	False
Score_2	0.9631	0.0176	False
Score_3	0.9459	0.0016	False
Score_4	0.8841	1.91×10^{-6}	False
Score_5	0.9019	1.05×10^{-5}	False

Table B.2: Kruskal–Wallis test results (EDA)

Numeric Variable	Categorical Group	H statistic	p-value
Score_2	Genere	7.9038	0.0049
Score_4	Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale	7.1523	0.0075
Score_1	Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale	3.2029	0.0735
Score_2	Titolo di studio più elevato	4.4905	0.1059
Score_1	Genere	2.1750	0.1403
Score_4	Titolo di studio più elevato	3.2751	0.1945
Score_2	Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale	1.4507	0.2284
Score_5	Genere	1.4446	0.2294
Score_4	Età	5.0360	0.2836
Score_1	Titolo di studio più elevato	1.5916	0.4512
Score_5	Titolo di studio più elevato	1.4745	0.4784
Score_3	Titolo di studio più elevato	1.4529	0.4836
Score_2	Età	3.4392	0.4872
Score_3	Genere	0.4526	0.5011
Score_3	Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale	0.3754	0.5401
Score_3	Età	3.0536	0.5489
Score_1	Età	2.8453	0.5840

Score_4	Genere	0.0491	0.8246
Score_5	Età	0.9468	0.9177
Score_5	Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale	0.00009	0.9924

Table B.3: Kruskal–Wallis test results (Statistical analysis)

Variable	Kruskal_stat	Epsilon_sq	Kruskal_p_fmt	Verdict
Score_4	15.35210657	0.17502569	<0.001	significant
Score_1	8.088168686	0.086441082	0.004	significant
Score_2	3.732798979	0.033326817	0.053	borderline
Score_3	0.708017521	0	0.400	not significant
Score_5	0.47137216	0	0.492	not significant

Table B.4: Mann–Whitney U test results (Statistical analysis)

Variable	U_stat	Median_0	Median_1	p_holm_fmt	Verdict
Score_1	410	2	3	0.005	significant
Score_2	856	2.67	2.33	0.054	borderline
Score_3	750.5	3	2.5	0.403	not significant
Score_4	314	2	3	<0.001	significant
Score_5	606.5	1.25	1.5	0.496	not significant

Table B.5: Chi-square test results (Statistical analysis)

Variable	Chi2_stat	Chi2_p	Chi2_p_fmt	Verdict
Titolo di studio più elevato	31.69917022	1.30801E−07	<0.001	significant
Esperienze lavorative in reparti di Terapia Intensiva diversi dalla Terapia Intensiva Neonatale	23.0224588	1.6012E−06	<0.001	significant
Genere	20.55025677	5.8086E−06	<0.001	significant
Età	14.22822337	0.006601179	0.007	significant
Stato civile	11.72083799	0.008403277	0.008	significant

List of Figures

List of Tables

Acknowledgments