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Implementing ISO 9001:2015 in Healthcare: The Experience of the Dermatology SCDU at AOU Maggiore della Carità of Novara

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ABSTRACT

Quality management in healthcare has become a global priority since the landmark 1999 Institute of Medicine report *To Err is Human*, which reframed medical errors as systemic rather than individual failures. In Italy, voluntary quality frameworks such as ISO 9001:2015 have emerged as strategic tools for healthcare organizations seeking continuous improvement beyond mandatory accreditation. This accreditation is recognized as a tool to systematically monitor performance, manage risk and drive continues improvement. This study presents a comprehensive analysis of the ISO 9001:2015 certification process implemented within the Dermatology and Venereology Unit (SCDU) of the "Maggiore della Carità" University Hospital in Novara, evaluating its effectiveness in improving clinical and organizational processes, risk management, and stakeholder satisfaction.

The quality management system was implemented following the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking as defined by the ISO 9001:2015 standard. Key methodological tools included SWOT analysis to assess the unit's strategic context, Key Performance Indicators (KPIs) to monitor clinical activity across all sub-specialties (dermo surgery, melanoma, cutaneous lymphomas, phototherapy, inflammatory skin diseases, paediatric dermatology, sexually transmitted infections, and clinical research), patient and staff satisfaction surveys, and systematic tracking of non-conformities and corrective actions. Data were collected over a three-year period (2023–2025).

Activity volumes showed an overall increase, particularly in Day Hospital admissions and multidisciplinary oncological assessments, alongside a growing catchment area, with patients from outside the local health authority rising from 26.6% in 2023 to 31.5% in 2025. Strong clinical response rates were recorded in biological therapy for psoriasis and atopic dermatitis, and in targeted therapies for locally advanced basal cell carcinoma (90% response rate). A total of 26 non-conformities were identified, predominantly in the operating room sector, linked to the reduction of anaesthesiologist coverage. Patient satisfaction remained consistently high, while staff satisfaction declined in 2025, highlighting structural resource constraints. Improvement projects for 2026 were defined in response to identified gaps, including the resumption of phototherapy services, expansion of telemedicine, and reinforcement of multidisciplinary collaboration.

In conclusion, ISO 9001:2015 certification provides a structured, evidence-based framework for making quality issues visible, measurable, and addressable in a complex clinical setting. The experience of the Novara Dermatology Unit demonstrates that a quality management system, when rigorously applied, enables continuous organisational learning and accountability.

Keywords: ISO 9001:2015, quality management, dermatology, patient safety, PDCA, SWOT analysis, KPIs, non-conformities, healthcare accreditation

1 INTRODUCTION

1.1 The concept of quality in healthcare

In 1999, the Institute of Medicine published a report that would mark a decisive turning point in the field of patient safety. The report highlighted the urgent need for reform that recognised patient safety as a global priority, thereby prompting institutions to strengthen quality standards in healthcare. Quality is defined as a multidimensional concept, a fundamental parameter for raising standards in healthcare provision. Consequently, healthcare organisations have responded by adopting international management systems and regulatory mechanisms designed to systematically monitor the quality of care delivered through internal and external audits.[1]

Despite the importance of guidelines, the traditional approach, which relies on the experience of individual experts, has often resulted in protocols that lack transparency and are out of touch with patients' actual needs. It is therefore necessary to adopt management systems that translate scientific evidence into clinical pathways that are genuinely applicable, measurable and outcome-oriented.[3]

Ensuring high standards of safety and quality of care is now a critical priority for healthcare systems worldwide. Problems often stem from systemic shortcomings, such as communication gaps between professionals, inadequate training programmes or organisational dysfunction. The quality of care is defined by the degree of adherence to validated scientific protocols and the ability to respond specifically to individual needs. The quality of healthcare is measured by the ability to combine the provision of effective, evidence-based treatments with the fulfilment of individual patients' needs, thereby reducing the risks arising from system failures.[2]

Accreditation is therefore an excellent way of improving the quality of hospital care, including that of a single department or a specific treatment.[4]

1.2 Historical development: From the concept of medical error to a culture of safety

Reflection on medical errors has very ancient roots: already the Code of Hammurabi (1792–1750 B.C.) included specific sanctions for doctors who caused harm to patients, showing that the responsibility of the doctor was recognized from the earliest civilizations. In modern times, it was the British jurist Sir William Blackstone who introduced, in 1765, the concept of mala praxis, from which the current notion of malpractice derives, defining it as 'negligence or ineffective management by a doctor or surgeon.' During the 19th and 20th centuries, there was a significant evolution in the concept of error in the legal field, with an increase in lawsuits, initially focused on errors of commission, that is, wrong actions actively carried out by the doctor (such as radiation injuries or surgical complications). Later, the focus shifted to errors of omission, meaning cases where the doctor was held responsible for not doing what would have been correct. An emblematic

example of this was the dramatic increase, between the early Seventies and the late Eighties, in lawsuits for missed cancer diagnoses. At the same time, in those years, malpractice claims skyrocketed, fuelling the spread of so-called defensive medicine: a practice where the doctor, driven by fear of accusations, resorts to excessive diagnoses or unnecessary procedures, with potentially harmful effects for the patient. This historical evolution reflects a deep change in how medical error is understood: from a punishable individual act to a complex phenomenon that involves not just the conduct of a single professional but the entire system in which care is delivered.[5] The concept of medical error has thus evolved over the course of history, undergoing a profound transformation: going from an individual act to a complex phenomenon, which involves not only the doctor but also the entire system in which care is provided. The consequences of this complexity are far from abstract: every clinical error and the related malpractice claims are indeed a growing problem in medical practice. The impacts affect both the patient, exposed to the risk of iatrogenic harm during hospitalization, and the healthcare system, increasingly raising costs and making them difficult to sustain.[6]

A turning point in this path came in 1999, when the Institute of Medicine (IOM) published the report To Err is Human: Building a Safer Health System.[7] The publication of this document helped launch not only the field of patient safety but also a broader interest in healthcare quality. Data recorded in the 1980s reported between 44,000 and 98,000 annual deaths in U.S. hospitals attributable to medical errors, numbers that captured the attention of the public and policymakers, although they remained subject to critical review in the following decades.

The most recent data confirm that the problem remains highly relevant, although estimates vary considerably depending on the methodology used. According to a 2024 analysis based on official data from the Centers for Disease Control and Prevention (CDC), the age-adjusted mortality rate for complications from medical and surgical care has increased from 1, 17 per 100,000 in 2018 to 1.49 per 100,000 in 2021, then dropping to 0.85 per 100,000 in 2022.[8] These fluctuations reflect not only changes in clinical practices but also the impact of contextual factors like the COVID-19 pandemic on the healthcare system. The fundamental merit of *To Err is Human*, however, was radically shifting the perspective: the most important insight of the patient safety movement was recognizing that errors are largely the result of inadequate systems, not inadequate people. This systemic view paved the way for a new paradigm, laying the groundwork for what we now call a safety culture.

A fundamental theoretical contribution to this shift in perspective came from the psychologist James Reason, in his article Human Error: Models and Management (BMJ, 2000). Reason distinguished between two opposing approaches to error management: the person approach and the system approach. The historically dominant concept in medicine is the first one, which sees error as the result of individual failings due to inattention, negligence, or lack of motivation, and responds with disciplinary measures. On the other hand,

the second approach starts from the assumption that humans are inherently fallible and that errors are a consequence of systemic factors. Reason stated, 'We cannot change the human condition, but we can change the conditions under which humans work' (Reason, 2000, p. 769). The Swiss cheese model, developed by Reason himself, shows how high-tech systems have multiple layers of defence, each of which has gaps, like holes in a slice of Swiss cheese. An adverse event only happens when the holes in several layers line up at the same time, allowing the error's path to pass through all the barriers. This metaphor made the multifactorial nature of clinical incidents visible and understandable, finally shifting the focus from individual blame to the system's structural weaknesses.[9]

One of the fundamental pillars of quality in healthcare is therefore the culture of patient safety, and its goal is to guide values, behaviors, and clinical practices toward preventing harm and continuously learning from mistakes. In a broader sense, the World Health Organization (WHO) defines patient safety as the absence of preventable harm and the reduction of risk associated with care to a minimally acceptable level. The culture of safety is not just a matter of visible behaviors but has deep roots in shared values. This concept is illustrated by the safety culture pyramid model, which starts with cultivating underlying values, goes through processes and an organized system, and then culminates in performance.[10] In this context, leadership plays a central role in shaping that culture, because leaders influence priorities, resources, and expectations that guide how staff approach safety management. Healthcare professionals' core values and attitudes significantly shape frontline safety culture; therefore, understanding their perceptions and securing top management commitment are essential for driving organization-wide continuous improvement.[11,12]Currently, this idea is expressed in the ISO 9001:2015 standard, chapter 5, which describes leadership as a key pillar for a proper quality management system.
Recent evidence confirms that patient safety culture remains a critical and often underdeveloped dimension in hospital settings: studies conducted in both teaching hospitals and paediatric intensive care units have highlighted persistent weaknesses in areas such as non-punitive responses to errors, interprofessional communication, and staffing, while also demonstrating that sustained investment in feedback mechanisms, organisational learning, and leadership commitment can drive meaningful and measurable improvements over time.[13,14]

1.3 Putting the patient first: How the patient's role has shifted from that of a passive recipient to that of an informed 'customer' of the healthcare service.

Patient-centered care (PCC) is now regarded as a cornerstone of a modern healthcare. The traditional biomedical approach, focused exclusively on treating disease, is being replaces by a broader bio-psyco-social perspective. This means viewing the patient holistically, with the aim of providing personalised care that

places the patient's needs, values and choices at the centre. The transition to this new model requires a profound practical shift: greater and more effective patient involvement becomes essential, as patients must be motivated to adopt self-management behaviours and to actively collaborate with healthcare professionals to define a personalised care plan. However, despite the importance of the model, there remains a gap between the expectations of healthcare professionals and the patient's actual capacity, self-efficacy and genuine willingness to take an active part in medical decisions concerning them.[15]

Optimizing patient-centred care requires a profound understanding of the needs of both patients and their caregivers, who must represent the focal point at every stage of the care pathway. Among the primary necessities, key elements include disease awareness and education, early diagnosis, access to specialized centres and specific treatments, symptom management, participation in clinical trials, and psychological support. In daily clinical practice, however, the accurate assessment of these needs is often hindered by time constraints. To overcome this limitation, the preliminary use of Patient-Reported Outcome Measures (PROMs) allows for the monitoring of disease impact and subjective well-being through self-reported health status. Complementarily, Patient-Reported Experience Measures (PREMs) enable the evaluation of the quality of care received, contributing to service improvement. Finally, it is essential to address the unmet needs of caregivers as well, providing them with adequate support strategies that include educational programs along with social and psychological support.[16]

Patient-centered care does not mean care dictated by the patient or detached from evidence-based medicine, but rather the integration of the best clinical evidence with the individual's psychosocial context and health priorities. This personalized approach evolves dynamically as the disease progresses and is practically achieved through the removal of socio-cultural barriers by multidisciplinary teams and the empowerment of patients in managing their therapies. Finally, the rigorous use of patient-reported outcomes (PROs), combined with physiological parameters, allows not only for the optimization of clinical decision-making but also for influencing scientific guidelines and global healthcare policies.[17]

Health Literacy (HL) represents the ability to access, understand, and apply health information to make informed therapeutic choices. Although a strong correlation exists between high HL and positive health behaviours, factors such as low educational attainment, socioeconomic vulnerability, and physical limitations often hinder its full development. Currently, despite the widespread availability of information tailored for non-specialists through digital media and institutional channels, scientific literature suffers from a lack of empirical evidence regarding how patients interpret such data and what priorities they assign to different aspects of care, leaving the patient's perspective within the care process still partially unexplored. This information gap directly reflects on treatment adherence, a cornerstone for ensuring quality of care and clinical success. Patient adherence is influenced by demographic and clinical variables (such as age, education, and ethnicity) but finds fundamental support in interpersonal communication and educational

interventions. In this context, Shared Decision Making (SDM) emerges as a key tool to promote patient self-efficacy and empowerment, placing the individual at the centre of the care pathway. However, the effectiveness of this synergy and the quality of the doctor-patient relationship can be heavily conditioned by the patient's educational background and language skills: indeed, patients with lower language proficiency tend to experience more negative interactions with professionals, unlike their highly educated counterparts. Finally, the definition of therapeutic priorities depends not only on the clinical context and patient characteristics (such as age and survival expectancy) but is also influenced by the ethical orientation of physician, particularly regarding resource allocation, and their actual willingness to consider the patient as a decision-making partner. Therefore, from both a policy and managerial perspective, it is essential to fully understand healthcare professionals' perceptions to foster a genuinely participatory model of care.[18,19]

1.4 The Institutional Context: The Dermatology SCDU in Novara

The "Maggiore della Carità" University Hospital in Novara is widely recognised as a centre of excellence within the Italian healthcare system, distinguished by its high standards of clinical care, its academic mission and its active engagement in scientific research. Its organisational structure reflects a deep commitment to the principles of quality management in healthcare, making it a particularly relevant and meaningful context for the application of the ISO 9001:2015 standard. It is within this institutional setting that the SCDU of Dermatology and Venereology carries out its clinical, educational and research activities.
The University-Managed Complex Unit (SCDU) of Dermatology and Venereology is part of the “Maggiore della Carità” University Hospital in Novara. Headed by Prof. Paola Savoia, the Unit is based within the Department of Specialist and Oncology and represents a centre of excellence for the diagnosis and treatment of all skin diseases (genetic, infectious, parasitic, allergic, immune-mediated and neoplastic). Clinical and care activities are divided between Pavilion G of the AOU in Novara and the San Rocco Hospital in Galliate. The SCDU is home to the School of Specialisation in Dermatology and Venereology of the University of Eastern Piedmont (UPO), dedicated to training future specialists. The unit also hosts ‘professional’ placements for students of the Master’s Degree Course in Medicine and Surgery at the UPO and actively promotes clinical and translational research projects in the field of dermatology.
The institutional mandate of the University-managed Complex Unit (SCDU) of Dermatology centres on the diagnosis and complex therapeutic management of dermatological conditions, encompassing both medical and surgical approaches. An area of particular interest for the Unit is oncological dermatologic surgery, focused on the treatment of epithelial skin tumours (non-melanoma skin cancer) and melanocytic tumours. This work employs a diverse methodological approach ranging from traditional excision techniques to highly specialised procedures, such as Mohs micrographic surgery, the Tübingen Mohs technique, electrochemotherapy and medical therapies for advanced neoplastic forms. Where the complexity of the clinical picture so requires, patient care is provided in collaboration with multidisciplinary teams, involving

specialists in medical Oncology, Radiotherapy, Plastic Surgery, Otolaryngology, Orthopaedics and General Surgery.

At the same time, clinical and care activities are carried out through a network of primary and secondary care clinics, designed to address a wide range of non-surgical conditions. These include infectious and sexually transmitted diseases, severe drug-induced toxic reactions, autoimmune bullous diseases and inflammatory skin conditions, as well as the management of burns, allergic conditions, skin manifestations in transplant patients and paediatric dermatological conditions. A further cornerstone of care is provided by rigorous follow-up programmes dedicated to patients with a history of melanoma or those with a genetic predisposition to skin cancers.

As a testament to its high level of specialisation, the Unit also serves as a centre of excellence for the medical management of psoriasis and moderate-to-severe atopic dermatitis, as well as for locally advanced basal cell carcinomas. Finally, the SCDU's academic vocation is realised through a fruitful commitment to clinical research in the fields of dermatology and dermo-oncology, and to academic training, ensuring a comprehensive learning pathway.[32]

1.4.1 Overview and mission of the SCUD

The operations of the Dermatology and Venereology SCDU at the "Maggiore della Carità" University Hospital in Novara are geared towards achieving standards of excellence, in line with the requirements for continuous improvement set out by ISO 9001 certification. The Unit has a clearly defined mission that aims to combine the efficiency of care processes with the high scientific rigour of university research. This is achieved through the creation of an ecosystem where patient care, staff training and scientific innovation interact with one another. This approach serves to guarantee high quality standards both in terms of individual patient safety and the effectiveness of treatment.

The SCDU provides comprehensive diagnostic and treatment pathways for a wide range of skin conditions, including genetic, infectious, parasitic, allergic, immune-mediated and neoplastic diseases. Clinical care is organised into distinct units comprising the Day Hospital and first- and second-level outpatient clinics, distributed between Pavilion G at the main site in Novara and the 'San Rocco' hospital in Galliate. Of particular importance is the dermatological-oncological surgery programme, which employs cutting-edge techniques (such as Mohs surgery) for the treatment of melanomas and carcinomas; in patients complaining of advanced forms of cancer follow up is warranted through the "Skin Cancer Unit", in strict collaboration with other Specialties.

As the home of the School of Specialisation in Dermatology and Venereology at the University of Eastern Piedmont (UPO), the SCDU plays a pivotal role in training the next generation of doctors and specialists. Training is delivered through professional placements for students on the Master's Degree course in Medicine and Surgery. This educational function is not merely an academic commitment but forms an

intrinsic part of the department's Quality Management System. The constant presence of postgraduate trainees and students fosters an environment of continuous dialogue and systematic professional development for the permanent staff. The transfer of knowledge and the standardisation of clinical procedures taught to future doctors ensure that internal expertise is always aligned with the latest international guidelines, meeting the ISO requirement regarding the management of human resources and organisational knowledge.

The third pillar of the department's mission is represented by intensive translational scientific research, carried out in collaboration with the laboratories of the Department of Health Sciences at the UPO. Research focuses on the mechanisms of photo-induced damage, the genetics of melanoma and the study of the microbiota, enabling patients to access innovative treatments through numerous ongoing clinical trials. Scientific findings are rapidly translated into daily clinical practice, allowing the department to constantly evolve its standards of care and offer increasingly effective and personalised therapeutic responses.[32]

1.4.2 Organisation of Services by Level of Complexity

The clinical activities of the Dermatology and Venereology SCDU are structured around two levels of care, first-level and second-level, designed to ensure an appropriate and differentiated response to patient needs. First-level care represents the initial point of entry for patients and encompasses initial dermatological consultations, check-ups, the management of emergencies, the treatment of burns, and referrals to other hospital wards via Fast Track pathways. The aim of this level is to monitor activity volumes and ensure compliance with pre-set waiting times.
Second-level care, on the other hand, represents the advanced specialist phase, dedicated to patients with chronic, rare, oncological or highly complex conditions. Care at this level is delivered through dedicated outpatient clinics and follows structured Diagnostic, Therapeutic and Care Pathways (PDTA), ensuring a multidisciplinary approach. This level includes, among others, the management of melanoma, cutaneous lymphomas, inflammatory skin diseases, sexually transmitted infections, dermatological conditions in paediatric patients, and organ transplant recipients requiring dermatological follow-up. Advanced medical treatments, including biological and systemic therapies, are provided within this framework in collaboration with other specialist units where required.[32]

1.4.3 Management of Medical Conditions: Pathways to Excellence

1.4.3.1 Oncology Unit (Dermatological Oncology)

The Oncology Unit represents the pinnacle of medical and surgical specialisation within the Department of Dermatology and Venereology, focused on ensuring the technical quality of care and services, with a view to the efficient use of resources and optimal operational organisation. The approach to oncological conditions is comprehensive and personalised: it begins with identifying patients suitable for surgery, continues with

determining the most appropriate procedure, and ensures careful post-operative monitoring through follow-up. In this context, the department utilises two specialist units: the dermosurgery unit and the non-melanoma skin cancer unit.[32]

1.4.3.1.1 Dermatologic Surgery

The Dermatologic Surgery Unit comprises professionals with proven experience and theoretical expertise in the surgical treatment of neoplastic conditions. Each patient's clinical pathway is reviewed and updated annually, and the most complex clinical cases are discussed collectively within the Interdisciplinary Care Group (ICG). Oncological dermatosurgical procedures are performed in a dedicated operating theatre equipped with specialist instruments, with the support of the anaesthesia team. To ensure high standards of care, the medical team follows a programme of continuous professional development; the clinical expertise acquired is regularly presented at conferences and published in national and international scientific journals. The surgical treatment of neoplastic conditions employs highly specialised techniques, particularly Mohs micrographic surgery (direct, deferred and Tubingen variant). This method is considered the 'gold standard' for recurrent basal cell carcinomas or those located in critical anatomical sites, as it allows for the maximum removal of the tumour whilst ensuring the greatest possible preservation of the surrounding healthy tissue.[20]The Mohs Tubingen technique represents the gold standard for a rare skin tumor, Dermatofibrosarcoma Protuberans, and it is offered only in a strict number of public Hospitals, including the Dermatology Surgery Unit in Novara.[21]

Access to dermatosurgical treatment within a day-hospital setting is contingent upon a preliminary specialist outpatient evaluation. Once the clinical indication is established, the patient is entered into the internal booking system in accordance with clinical priority categories. During the subsequent pre-admission phase, concurrently with the opening of the medical record, the physician provides a comprehensive overview of the surgical procedure, including expected benefits and potential risks. After addressing any queries regarding the post-operative course, the information process is formalised through the patient's signing of the informed consent form for both medical treatment and the processing of personal data.[32]

1.4.3.1.2 Melanoma Unit and Genetics

The management of patients with melanoma is comprehensive and multidisciplinary, ranging from the primary lesion excision to any revision of the surgical scar, or the performance of the sentinel lymph node biopsy. Once the surgical procedure is complete, the patient is enrolled in a clinical and diagnostic follow-up programme. Depending on the stage of the disease, the Melanoma Unit works in consultation with oncologists to determine eligibility for systemic therapies. Staging is carried out in accordance with the international classification of the American Joint Committee on Cancer (AJCC), 8th edition.

The follow-up of patients who have undergone surgery for cutaneous melanoma is a process strictly governed by the PDTAs (Diagnostic and Therapeutic Algorithms) specific to the condition, which are

constantly updated and aligned with national and international guidelines. The aim is long-term monitoring through a thorough clinical examination, supported by the routine use of a manual dermoscope and video dermoscope, focusing on the scar area and lymph node regions for the early detection of disease recurrence, whether in the form of cutaneous or subcutaneous metastases, or lymph node metastases. This approach is supplemented by instrumental staging examinations (upper and lower abdominal ultrasound, lymph node station ultrasound, whole-body CT with contrast, whole-body PET), tailored to the stage of the melanoma. For more complex clinical cases, particularly for metastatic patients undergoing immunotherapy and targeted therapy, follow-up is carried out in collaboration with the oncology department and patients are scheduled for periodic evaluation by both the healthcare workers in the "Melanoma Unit". Treatment strategies or the initiation of palliative care are discussed during multidisciplinary team meetings supported by the Interdisciplinary Care Group (GIC). In selected cases involving cutaneous metastases, locoregional treatments such as electrochemotherapy are used. Waiting times are kept to a minimum as regular follow-up appointments are scheduled in advance; furthermore, the entire care pathway is based on sharing treatment decisions with the patient, including educational activities on healthy lifestyles. The excellence of these care pathways is guaranteed by the continuous training of dedicated staff, who actively participate in the 'Piedmont Oncology Network', ensuring that care standards are always up to date.

Patients affected by locally advanced or metastatic Squamous Cell Carcinoma, thus requiring to start immunecheckpoint inhibitors therapy are also in charge at the Melanoma Unit, since they could benefit from the jointly dermatological and oncological clinical evaluation. The scheduled examinations are scheduled in advance.

Concerning patients with locally advanced Basal Carcinoma, the recently developed target therapies acting on the Hedgehog pathways are administered, and those subjects are evaluated according to their clinical needs and to the necessity of periodical evaluations as well as for the prescription of drugs, that is allowed according to specific requirement in accordance with AIFA.[32]

1.4.3.1.3 Cutaneous Lymphomas

Following an initial assessment by a dermatologist and/or haematologist, based on a confirmed or strongly suspected histopathological diagnosis of cutaneous lymphoma, patients may be referred to the secondary-level dermatology clinic. This clinic is dedicated to patients diagnosed with primary cutaneous lymphoma and haematological disorders with secondary cutaneous involvement. As evidence of this multidisciplinary approach, a joint clinic with the Haematology SCDU has been operational since December 2024 and conducts around 20 outpatient consultations per month. The consultations, conducted jointly by a dermatologist and a haematologist, ensure integrated management for staging and the administration of systemic, oral or physical therapies, optimising continuity of care for the onco-haematological patient. The initial dermatological-haematological consultation and periodic clinical follow-up assessments involve a

comprehensive evaluation of the patient, including a cardiopulmonary and abdominal assessment, a clinical and dermoscopic examination of the skin, palpation of lymph nodes, and assessment of lesions, post-operative scars or post-radiotherapy scars. Instrumental monitoring is necessary to assess the progression of the disease and is tailored to the clinical stage. All doctors and healthcare professionals undergo continuous professional development through specific courses and conferences. Patients are managed according to specific PDTA protocols; furthermore, the entire diagnostic and therapeutic care pathway is shared and explained in detail from the moment of diagnosis, covering the possible progression of the disease, follow-up, and the timing of clinical and diagnostic examinations, right through to the types of treatments that are proposed and may become necessary during the course of the disease.[32]

1.4.3.1.4 Phototherapy and Photodynamic Therapy Unit

Phototherapy is a treatment modality that involves exposing the affected skin to ultraviolet (UV) radiation; it can be administered to specific localized areas or involve the entire body. Currently, this therapy is the treatment of choice for various dermatological conditions, including psoriasis, atopic dermatitis, prurigo eczema, parapsoriasis, pityriasis lichenoides, hematological disorders with cutaneous involvement (such as lymphomatoid papulosis and early-stage mycosis fungoides), and maculopapular mastocytosis.

Specifically, the following treatment protocols can be performed:

1. UVB therapy (TL-01, i.e., narrowband)
2. COMBI UVA-UVB (combined therapy utilizing both UV frequencies)
3. Partial UVA for the hands
4. Partial UVA for the legs and feet
5. Combined UVA for the hands and feet
6. PUVA therapy (following oral administration of 8-methoxypsoralen, or 8-MOP)
7. Bath-PUVA therapy (medicated baths in a tub containing 0.5% 8-MOP followed by UVA exposure)
8. Gel-PUVA therapy (topical application of a 0.05% 8-MOP gel followed by UVA exposure)
9. Re-PUVA therapy (oral premedication with acitretin prior to PUVA).

Photodynamic Therapy (PDT) represents a non-invasive dermatological treatment based on the use of a red LED light source (with a wavelength of 630 nm) to activate methyl aminolevulinate (MAL), a topical photosensitizing agent. This interaction leads to the production of reactive oxygen species (free radicals) capable of inducing cytotoxicity and the subsequent destruction of target cells via apoptosis. A methodological variant is daylight PDT, in which the activation of MAL occurs through exposure to sunlight.

Since the solar emission spectrum is not strictly selective for the drug, this procedure requires more prolonged outdoor exposure times (approximately two hours) to ensure an adequate photodynamic yield. However, it remains dependent on weather and climatic conditions, rendering it inapplicable during the winter months or on days with poor insolation.

Clinically, the primary indication for PDT is the treatment of neoplastic and precancerous lesions, such as basal cell carcinoma, actinic keratosis, and Bowen's disease, although it is also utilized as a second-line option for acne, warts, and photoaging. In therapeutic protocols dedicated to oncological and pre-tumoral pathologies, the treatment may involve the administration of two sessions spaced a few weeks apart. Today, this methodology stands as a gold standard for therapeutic efficacy, particularly in the management of actinic keratoses, where it provides excellent curative outcomes and plays a significant preventive role in clinical presentations characterized by severe, chronic actinic damage.

The Phototherapy and Photodynamic Therapy (PDT) Service, located at the outpatient clinics of the San Rocco Hospital in Galliate (affiliated with the Novara facility), guarantees care pathways based on international scientific guidelines and delivered by continuously trained personnel. Access to treatments, which is strictly subject to a prior dermatological evaluation, follows distinct organizational dynamics for the two methodologies. Phototherapy structured over two days a week with continuous medical and nursing monitoring, as well as interdisciplinary pathways for hematological patients, provided approximately 500 sessions in 2024. However, the service is currently operating at a reduced capacity due to the temporary unavailability of the *total body* and UVA cabins, making waiting times unquantifiable pending a full resumption of activities scheduled for 2026. Conversely, the PDT service is fully operational and expanding, having increased from 80 procedures in 2024 to 104 in 2025, with estimated waiting times of 1 to 2 months. The monthly photodynamic sessions utilize two dedicated LED lamps, as well as outdoor spaces (the ward terrace and the hospital garden) for the *daylight* variant, involving a medical-nursing team in all procedural phases—from lesion curettage and photosensitizer application to outpatient follow-up. This clinical-organizational framework consolidates the absolute relevance of these therapies within the dermatological landscape, confirming PDT, in particular, as a treatment of excellence and a first-line choice (Grade A recommendation) for the management of actinic keratosis.[32]

1.4.3.2 Chronic and Inflammatory Diseases Unit

This unit manages systemic conditions with a chronic-relapsing course (such as psoriasis, atopic dermatitis and hidradenitis suppurativa) that have a serious impact on the patient’s quality of life. The clinical management of patients affected by moderate-to-severe inflammatory skin diseases is based on a rigorous diagnostic and therapeutic pathway. Access to the second-level outpatient clinics occurs upon referral by outpatient specialists, general practitioners, or colleagues from other medical disciplines (such as rheumatologists, allergists, and surgeons), often following a prior multidisciplinary discussion of the clinical

case. These second-level outpatient clinics receive patients from the province of Novara, from other provinces in Piedmont, as well as from other Italian regions, most notably from neighboring Lombardy.

The choice of treatment is carefully tailored based on the clinical evaluation, the results of blood and instrumental tests, comorbidities, and ongoing polytherapies, operating in strict adherence to national and international guidelines as well as regional directives. Specifically, for severe skin diseases (such as psoriasis and atopic dermatitis) that prove refractory to previous topical treatments, the team evaluates the patient's eligibility for traditional systemic therapies or the use of biologic drugs. The patient is then enrolled in a structured follow-up program that includes periodic check-ups for continuous clinical and laboratory monitoring, the issuance or renewal of therapeutic plans, and, for more complex clinical scenarios, multidisciplinary management through targeted specialist consultations. To optimize logistical and healthcare support, direct communication channels via email dedicated to specific pathologies are also active. This robust care framework is guaranteed by professionals undergoing continuous medical education and who are actively engaged in research. The facility, in fact, participates in multiple national study projects and boasts a solid scientific output, evidenced by numerous papers regarding the management of these diseases published in the literature and presented at prestigious conferences.[32]

1.4.3.3 Specialised Pathways for Vulnerable Populations

1.4.3.3.1 Paediatric Dermatology

The Pediatric Dermatology Clinic is dedicated to the diagnostic evaluation and treatment of cutaneous disorders from the neonatal period through adolescence. This second-level service represents a key referral center for a broad patient population, receiving individuals from the province of Novara, the wider Piedmont region, and neighboring areas such as Lombardy and the Aosta Valley. Access to the clinic is granted upon direct referral from first-level facilities or by primary care pediatricians and hospital specialists, following a multidisciplinary discussion of clinical cases that require an integrated approach or are refractory to first-line treatments. The clinic’s medical activity covers a wide spectrum of conditions, including psoriasis, atopic dermatitis, hemangiomas and vascular malformations, infectious diseases, genodermatoses, rare diseases, alopecia, acne, autoimmune dermatoses, skin tumors, mastocytosis (urticaria pigmentosa), urticaria, and vitiligo. Patient management is heavily centered on interdisciplinary synergy; the facility actively collaborates with the SCDU Pediatrics, the SS Neonatology, the SCDO Pediatric Surgery, and the Pediatric Oncohematology Service. Within this framework, a joint monthly Pediatric Dermo-Allergology clinic is held to address the most complex cases, alongside multidisciplinary visits and consultations for patients referred by the pediatric Emergency Department. The clinic’s procedural and surgical offerings include videodermoscopy, cryotherapy, advanced dressings for burns and wounds, and minor surgical procedures (such as biopsies and excisions of cutaneous lesions) performed under local anesthesia or deep sedation. From a therapeutic standpoint, and in strict adherence to national and international guidelines, the medical team evaluates

patients with severe forms of psoriasis and atopic dermatitis for the initiation of traditional systemic therapies or systemic treatments with biologic drugs approved by AIFA or currently under clinical trials, following appropriate laboratory and instrumental screenings. Furthermore, the clinic is recognized as a regional referral center in Piedmont for the management of high-risk infantile hemangiomas with significant functional impact, which are treated via systemic or topical beta-blocker therapy (propranolol, timolol). The clinical pathway includes a structured follow-up program for periodic monitoring and targeted specialist consultations for comorbidities, supported by a dedicated communication channel available to patients. Staffed by a medical team deeply committed to continuous medical education, the service aims to increase its clinical caseload, expand its operating days, and enhance its participation in multicenter pediatric clinical trials as part of its future objectives.[32]

1.4.3.3.2 Follow-up of Transplant Patients

Organ transplant recipients undergo long-term immunosuppressive therapy; this treatment leads to an increased incidence of skin conditions, primarily of infectious and neoplastic origin. There is therefore a dedicated clinic for these patients where regular check-ups are carried out over time; the frequency of these check-ups is determined by the doctor based on various factors (skin characteristics, history of previous skin conditions, sun exposure, etc.). [32] Since a high number of patients are kidney transplant recipient, a strict collaboration with the local Kidney Transplant Unit is in place, thus allowing better and tailored cures.[32]

1.4.3.4 Specialised pathways for Infectious Diseases

1.4.3.4.1 Sexually Transmitted Diseases

The outpatient clinic dedicated to Sexually Transmitted Infections (STIs) represents a second-level referral center, integrated into the Piedmont regional network, specifically tasked with the diagnostic evaluation, treatment, and prevention of mucocutaneous pathologies with predominantly sexual transmission. The facility caters to a vast catchment area, receiving patients from the province of Novara, neighboring territories, and extra-regional areas. Access to the service, which was formerly walk-in, currently requires prior booking through first-level facilities or referral by General Practitioners, primary care pediatricians, and specialists. This necessary organizational restructuring has inevitably affected activity volumes, shifting from approximately 600 annual visits in the pre-2020 period to 270 recorded in 2024, with an upward trend to 296 consultations in 2025.

The clinical scope covers a broad spectrum of conditions, including syphilis, urethritis (caused by *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma*, and other pathogens), genital condylomatosis, HPV-related conditions, molluscum contagiosum, candidiasis, balanitis, vaginitis, and proctitis. Operating in strict adherence to national and international guidelines, the medical team performs comprehensive venereological screenings (serologies and molecular/cultural swabs with direct laboratory processing),

administers specific medical therapies (including intramuscular injections for syphilis and gonorrhea), and performs outpatient physical and surgical treatments such as cryotherapy, curettage, and diathermocoagulation.

The clinical management of patients is heavily multidisciplinary, utilizing joint visits and consultations with General Surgery (for proctological lesions), the SCDO of Infectious Diseases (for cases requiring hospitalization or parenteral therapies), the SCDU of Pediatrics (for pediatric and mother-to-child transmitted STIs), and the SCDU of Gynecology and Obstetrics, in addition to providing support to the general, gynecological, and pediatric Emergency Departments. Beyond ensuring a rigorous follow-up pathway, the center is distinguished by its patient-centered care: it offers preventive counseling services, provides a dedicated telephone line, employs cultural mediators to overcome language barriers, and is actively integrated into the hospital protocol for the management and protection of victims of sexual violence or exploitation.[32]

1.4.3.5 First-Level Outpatient Activities

First-level outpatient activities are provided by a team of 12 dermatologists, with on-duty service from Monday to Friday from 8 AM to 8 PM and on Saturday from 8 AM to 2 PM. There is also an on-call service on Sundays and public holidays from 8 AM to 8 PM, ensuring continuous care coverage throughout the week.

The first-level clinic offers various dermatology appointments, including initial visits, follow-ups, and urgent visits, which can be booked through the CUP (Centro Unificato di Prenotazione: Central Booking Unit). The service also includes consultations in other hospital departments, the Emergency and Acceptance Department (DEA), the Dermatology Fast Track, and other hospitals in the area, ensuring wide accessibility and integration with the healthcare network. [32]

1.5 The Italian Healthcare Quality Framework

In Italy, healthcare quality governance operates through a dual-track system: mandatory institutional accreditation, regulated at the regional level under Legislative Decree 502/1992, and voluntary third-party certifications such as ISO 9001:2015 and Joint Commission International (JCI). This framework was further strengthened by Law 24/2017, known as the "Gelli-Bianco Law," which recognized patient safety as a fundamental right and mandated the establishment of clinical risk management structures in all public and private accredited healthcare facilities (Fumai et al., 2026). Within this regulatory context, voluntary quality standards such as ISO 9001:2015 have emerged as a strategic tool for Italian healthcare organizations seeking to go beyond mere compliance and pursue continuous improvement in clinical processes and patient safety.[22]

1.6 Regulatory Framework

The pursuit of quality and safety in healthcare is not only an ethical imperative but also a legal obligation, governed by a complex body of national and European legislation. The key legislative and regulatory references applicable to the SCDU of Dermatology and Venereology of the AOU "Maggiore della Carità" of Novara are summarised in the table below.

REFERENCE	KEY CONTENT
LAWS AND REGULATIONS	
Law 833/1978	Establishment of the National Health Service (SSN)
Legislative Decree 502/1992	Organisation of healthcare companies
Legislative Decree 229/1999	Integration and improvement of the national health system
Legislative Decree 81/2008	Consolidated Law on Health and Safety at Work
Law 190/2012	Provisions for the prevention and suppression of corruption and illegality in Public Administration
EU Regulation 2016/679	Protection of personal data (GDPR)
Legislative Decree 101/2018	Code on the protection of personal data, adapting national legislation to EU Regulation 2016/679
EU Regulation 745-746/2017	Regulation on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/CEE and 93/42/CEE

Legislative Decree 219/2006	Regulation on medicinal products
Law 24/2017	Provisions on the safety of care and the assisted person, and on the liability of healthcare professionals
Law 94/1998	Off-label prescription (Bella Law)
Law 219/2017	Rules on informed consent and advance treatment directives
Ministerial Recommendation No. 18	Ministerial recommendation for the prevention of medication errors related to the use of abbreviations
DCR 616/2000	Manual of minimum accreditation requirements for public and private facilities
EU Regulation 20/2001	Directive 2001/20/EC on the approximation of laws, regulations and administrative provisions relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
EU Regulation 28/2005	Commission Directive 2005/28/EC laying down principles and guidelines for good clinical practice as regards investigational medicinal products for human use
EU Regulation 536/2014	Regulation on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC
EU Regulation 556/2017	Commission Implementing Regulation on the detailed arrangements for good clinical practice

	inspection procedures pursuant to Regulation (EU) No 536/2014
DPR 14/01/1997	Accreditation and authorisation of healthcare facilities — minimum structural and organisational requirements
D.P.R. 254/2003	Management of healthcare waste
DM 19/03/2015	Fire safety in healthcare facilities
STANDARDS	
ISO 9001:2015 (ver. 4)	ISO 9001:2015 Quality Management Systems Standard
Declaration of Helsinki	WMA Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Participants

Table 1: Key legislative and regulatory references for the Italian National Health System

Within the regulatory context, adopting the ISO 9001:2015 standard represents an ambitious choice by the organization, since this type of certification is not mandatory, giving the unit a structured and internationally recognized framework to implement, monitor, and continuously improve its quality management system, going beyond simple legal compliance.
The clinical research activities carried out within the unit are conducted in accordance with the ethical principles established by the World Medical Association Declaration of Helsinki, which sets out the fundamental ethical standards for medical research involving human participants, including research using identifiable human material or data.[23]

1.7 Quality Management Systems and Accreditation: the ISO 9001:2015 Standard

The ISO 9001:2015 standard is an international standard developed by the International Organization for Standardization that defines the requirements needed to implement a quality management system (QMS) within an organization.[24,25] It is a globally recognized standard, applicable to any organization regardless of its size or sector, that provides the necessary resources to improve performance based on the plan-do-check-act cycle principle, in order to achieve continuous improvement.[24]The standard, created in 1987 and revised several times over the years, has gradually evolved its approach toward continuous improvement, emphasizing customer satisfaction, management involvement, and process management. Among the main innovations of the 2015 version is the risk-based approach.[26] The identification of risks and opportunities is carried out using tools like SWOT analysis and the FMEA methodology: the latter involves assessing the criticality of an event through the product of three factors corresponding to severity, likelihood of occurrence, and the ability to detect the event itself.[27] In the healthcare field, adopting this standard helps improve overall performance and provides a foundation for ongoing development and progress.[25] In this context, a recent scoping review confirmed that, within the Italian National Health Service, ISO 9001:2015 adoption has produced documented benefits in terms of risk management, internal audits, and continuous process improvement, while highlighting increased logistical and organizational activities as the main barrier to implementation. Certification, accredited by a reputable body, serves as proof of credibility and professionalism for organizations worldwide.[26] In the Italian healthcare context, ISO 9001:2015 represents the most widely studied voluntary framework, with 73.3% of adopting organizations reporting improvements in processes and continuous quality.[23]

2. SCOPE

This paper aims to describe and analyze the ISO 9001:2015 certification process undertaken by the Dermatology Department of Novara Hospital. In detail, it will examine the tools and methodologies adopted for implementing the quality management system, including SWOT analysis and the Plan-Do-Check-Act (PDCA) cycle, evaluating their effectiveness in the continuous improvement of clinical and organizational processes, risk management, and stakeholder satisfaction. The analysis will also encompass the monitoring of key performance indicators, the management of non-conformities and corrective actions, and the identification of improvement projects, with the ultimate goal of showing how ISO 9001:2015 certification is a key tool for ensuring high standards of quality and safety in dermatology. This work is intended to illustrate a structured trajectory for enhancing healthcare quality standards.

3. MATERIALS AND METHODS

3. 1 General Information

A quality management system is a fundamental element for any organisation; it helps to improve its overall performance and build a solid foundation for sustainable development initiatives. The implementation of this system, based on this international standard, can deliver multiple benefits at both the operational and strategic levels. It ensures the ability to consistently provide products and services that meet customer requirements and applicable statutory and regulatory requirements, facilitating processes aimed at enhancing customer satisfaction. Furthermore, the system provides a structured approach to addressing the risks and opportunities associated with its context and objectives, offering the necessary tools to objectively demonstrate compliance with specified quality requirements. This international standard can be used by internal and external parties; furthermore, it does not impose as binding the uniformity of the structure of different quality management systems, the strict alignment of documentation with the chapters of the standard, or the obligation to adopt its specific terminology within the organisation's practices. The requirements for products and services are complementary to those proposed by the standard.

To achieve these objectives, the methodological framework of the standard is inherently based on the adoption of a process-based approach. This key principle underpins the development, implementation, and continuous improvement of the quality management system, serving as a primary tool for enhancing customer satisfaction through the systematic fulfilment of requirements. Understanding and correctly managing related processes as a system make a decisive contribution to organisational effectiveness and efficiency, allowing for the monitoring and coordination of the complex interrelationships and interdependencies between the various nodes of the system, thereby optimising the overall performance of the entire structure. With this in mind, the process-based approach requires the systematic mapping and rigorous management of activities and their mutual interactions, operating in strict alignment with the quality policy and the company's strategic guidelines. This integrated management of the system is achieved by synergistically integrating the Plan-Do-Check-Act (PDCA) cycle and so-called risk-based thinking. Specifically, the use of the PDCA cycle ensures that processes are adequately supported in terms of resources and managed efficiently, facilitating the identification and timely implementation of improvement measures. At the same time, risk-based thinking enables the proactive mapping of factors that could cause the system to deviate from expected results, introducing proactive controls aimed at minimising negative impacts, preventing undesirable outcomes, and capitalising on emerging opportunities.
From a strictly operational perspective, the implementation of this comprehensive methodology offers a number of benefits: it fosters a consistent understanding of and effective compliance with requirements; it enables each individual process to be assessed in terms of its actual added value; it ensures the achievement

of optimal performance; and, finally, it promotes the continuous optimisation of activities based on the objective analysis of data and information. Ultimately, this structural framework is essential for operating in modern contexts, which are historically dynamic and complex; in such scenarios, consistent performance and the anticipation of future needs require responses that go beyond the logic of simple correction or continuous improvement, extending to more profound interventions such as breakthrough change, innovation and structural reorganisation.

Getting ISO 9001:2015 certified follows a structured process that starts with defining the scope of the certification, followed by an optional gap analysis to see where the organization currently stands in terms of compliance. The formal certification audit is then done in two stages: an initial review of the documentation and a main on-site assessment, which, if successful, leads to a certificate that's valid for three years. Ongoing compliance is checked with annual surveillance audits, and at the end of the cycle, a full recertification audit is required.[33]

3.1.1 Plan-Do-Check-Act (PDCA) cycle

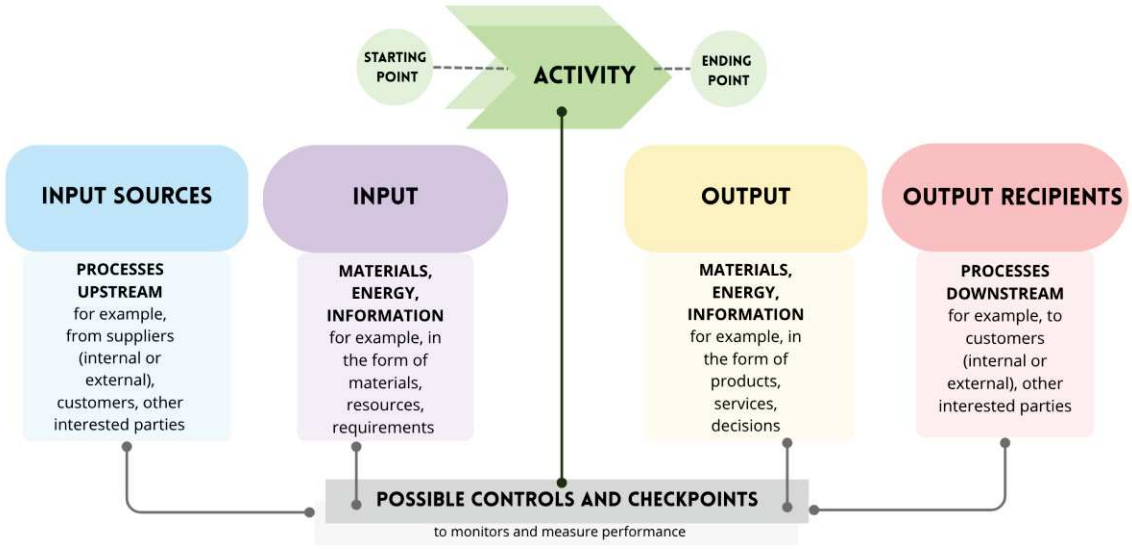


Figure 1: Schematic representation of the elements of a single process

The Plan–Do–Check–Act (PDCA) cycle is a widely recognized management tool, used in various sectors to promote continuous quality improvement through four sequential phases: planning, doing, checking, and corrective action. Continuous improvement within the hospital sector is promoted through the effective identification and resolution of problems, evaluating patient feedback with a focus on their needs, and better

communication and collaboration among healthcare team members. The PDCA cycle is a systemic process often used in research as a way to identify potential solutions to complex problems involving multiple functions. The four phases of this cycle bear a close resemblance to the scientific method, so hypothesis formulation, data collection and analysis from which conclusions are drawn.[28]

A common limitation of previous literature lies in the overlap between routine quality control (QC) and the PDCA cycle. While QC focuses on random and retrospective inspections with fragmented corrective actions, the PDCA model acts as a closed-loop mechanism for continuous improvement. The four phases referred to are: 22planning (Plan), implementing training and procedural changes (Do), checking through quantifiable metrics (Check), and taking corrective action directly on front-line clinicians (Act). This continuous dynamic allows for stable and structural quality gains in healthcare documentation, avoiding the typical overestimations of standard checks.[29]

Widely used to standardize practices and improve the quality of care, the PDCA cycle has proven very effective in hospital quality management and has also been successfully used to optimize workflows and emergency management in clinical settings. A concrete example is its use in improving the management of critical values, where the iterative approach has been shown to significantly raise standardization levels and the effectiveness of safety protocols.[30,31]

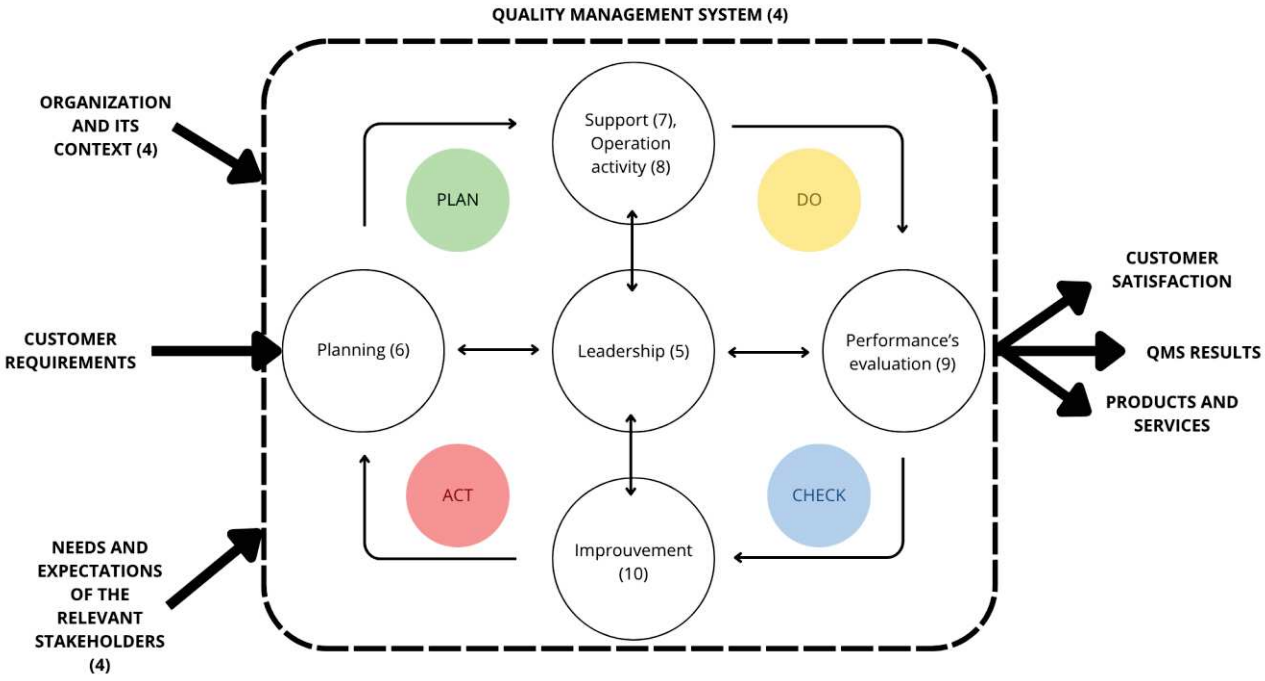


Figure 2: Representation of the structure of this International Standard in the PDCA cycle.

Note: The numbers in brackets refer to the clauses of this International Standard.

3.1.2 Risk-based Thinking

Risk-based thinking is a concept based on the obligation of an organization to plan and implement actions that address risks and opportunities. It is essential for achieving an effective quality management system. This allows building a foundation to increase the effectiveness of your quality management system, achieving better results and preventing adverse effects. Opportunities can be defined as the outcome of a situation favourable to achieving an expected result; in the medical field, we can see how these translate into the adoption of new clinical practices, enhancing the skills of healthcare staff, strengthening relationships with stakeholders, and improving the quality and safety of care provided to patients. However, every action taken to seize an opportunity comes with associated risks. Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. A positive deviation resulting from a risk can provide an opportunity, but not all positive effects of a risk turn into opportunities. The concept of risk-based thinking was already present, although implicitly, in previous versions of the standard. It showed up, for example, through taking preventive actions to eliminate potential nonconformities, analysing nonconformities that had already occurred, and implementing corrective measures to prevent them from happening again.[33]

3.2 Quality management principles

The methodological framework of the ISO 9001 standard incorporates and applies the fundamental principles of quality management formally described within the ISO 9000 standard. Each of these pillars is explored through a structured analysis that sets out its logical basis, the associated strategic benefits, and the typical courses of action aimed at optimising the organisation's overall performance. Specifically, the systemic framework is structured around seven principles: customer focus, aimed at meeting patient requirements; leadership, essential for ensuring unity of purpose and strategic direction; and the active involvement of people, which values and empowers human capital at every level of the organisation. These elements are complemented by a process-based approach, designed to manage interconnected activities as a coherent and predictable system, and a constant focus on continuous improvement. Finally, the scientific governance of the system is underpinned by evidence-based decision-making, which favours the objective analysis of data and information over empirical assessments, and by relationship management, aimed at optimising collaborative relationships with relevant stakeholders to maximise the value chain.[33]

In summary, the seven quality management principles defined by ISO 9000 and formally incorporated into the ISO 9001:2015 framework are listed in the table below.

Clause	Title	Description
1	Scope	Defines the requirements that an organisation must meet to demonstrate its ability to consistently

		provide products and services that satisfy customer and regulatory requirements
2	Normative references	Identifies the reference documents indispensable for the application of the standard, specifically ISO 9000:2015
3	Terms and definitions	Establishes the terminology and concepts applicable to the standard, as defined in ISO 9000:2015
4	Context of the organisation	Requires the organisation to understand its internal and external environment, the needs of relevant stakeholders, and to define the scope of its QMS
5	Leadership	Addresses top management's commitment, the establishment of quality policy, and the assignment of roles, responsibilities and authorities
6	Planning	Covers the identification of risks and opportunities, the setting of quality objectives, and the planning of changes to the QMS
7	Support	Encompasses the management of resources, competence, awareness, communication, and documented information
8	Operation	Deals with the planning and control of operational processes, including the design and delivery of products and services
9	Performance evaluation	Requires monitoring, measurement, analysis and evaluation of the QMS, including internal audits and management reviews
10	Improvement	Addresses nonconformities, corrective actions, and the commitment to continual improvement of the QMS

Table 2: Clause structure of the ISO 9001:2015 standard (adapted from UNI EN ISO 9001:2015)

3.3 ISO 9001:2015 Key Points

3.3.1 Scope

The International Standard ISO 9001 specifies the requirements for a Quality Management System (QMS) applied to the “Maggiore della Carità” University Hospital of Novara, demonstrating the organization’s ability to consistently provide healthcare services that meet patient and institutional partner requirements, as well as applicable statutory and regulatory requirements within the healthcare sector. Furthermore, it aims to

enhance patient satisfaction through the effective application of the system, including processes for the continuous improvement of clinical, care-related, and organizational performance.[33]The scope of the Quality Management System specifically encompasses the following healthcare activities and services:

- Diagnostic Services: Activities relating to laboratory testing, diagnostic imaging, outpatient specialized medicine, and all procedures aimed at identifying the patient's health status.
- Treatment and Therapy: Delivery of medical therapies, surgical interventions, rehabilitation pathways, and personalized therapeutic regimens.
- Patient Care: Comprehensive management of the patient throughout the care pathway, including admission, hospitalization, nursing support, patient safety, and continuity of care.
- Administrative Support: Admission and booking services, medical records and documentation management, healthcare information flows, privacy management, and secretarial activities supporting clinical operations.

3.3.2 Normative References

To ensure full legal compliance and the highest standards of patient safety, the implementation of the ISO 9001:2015 standard within the healthcare structure is strategically aligned with both national and international healthcare regulations. Rather than operating as an isolated quality framework, the Quality Management System (QMS) integrates the mandatory requirements established by national legislation, specifically the institutional authorization and accreditation systems of the Italian National Health Service (Servizio Sanitario Nazionale – SSN). This synergy ensures that quality objectives directly support clinical risk management and patient safety protocols, minimizing adverse events. Furthermore, the system complies with international and European regulations, including the General Data Protection Regulation (GDPR – Regulation EU 2016/679) for the secure management of sensitive health data, and the Medical Devices Regulation (MDR – Regulation EU 2017/745). By embedding these statutory and regulatory constraints into the ISO 9001 processes, from diagnostic services to direct patient care, the organization establishes a robust, legally compliant environment where clinical excellence and continuous quality improvement are structurally linked to the safeguarding of patient health.[33]

3.3.3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply. However, to ensure a precise translation of general quality management principles into the

healthcare context of the “Maggiore della Carità” University Hospital of Novara, the following healthcare-specific terms and definitions are established and applied throughout this system:

1. Patient (formerly “Customer” / “Client”): The primary recipient of healthcare services, including individuals seeking diagnostic procedures, medical treatment, nursing care, or rehabilitation. In the context of this QMS, patient satisfaction and patient safety represent the core objectives of all organizational processes.
2. Medical Record (or Health Record): A comprehensive, legally binding, and confidential document (either physical or digital, such as the Electronic Health Record – EHR) that systematically records a patient's medical history, clinical assessments, diagnostic test results, surgical reports, therapies, and progress notes.
3. Clinical Process: A structured sequence of interrelated clinical activities, decisions, and interventions—performed by multidisciplinary healthcare professionals—aimed at achieving a specific health outcome for the patient (e.g., the emergency admission process, the surgical pathway, or the diagnostic workflow).
4. Clinical Risk Management: A set of clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury or adverse events to patients, staff, and visitors within the hospital, directly aligned with patient safety protocols.
5. Informed Consent: The voluntary and documented agreement provided by a patient to undergo a specific medical intervention, surgery, or diagnostic procedure, after receiving comprehensive and understandable information regarding the risks, benefits, and alternatives.

3.3.4 Context of the Organization

In accordance with the requirements of clause 4.1 of ISO 9001:2015 standard, the "Maggiore della Carità" University Hospital of Novara systematically evaluates the internal and external factors that influence its strategic direction and its ability to achieve the expected healthcare outcomes for its quality management system. The understanding of the external context involves monitoring the evolution of healthcare regulations issued by the Ministry of Health and regional authorities, fast-paced advancements in medical technology, and socioeconomic trends that alter public health

demands. Regarding the understanding of the internal context, the hospital continuously assesses its tangible and intangible assets, including hospital infrastructure, clinical knowledge, organizational culture, and overall operational performance. Internally, a healthcare setting must evaluate elements such as the hospital infrastructure, medical equipment, hardware, software, communication systems (clause 7.1.3), staff competence and availability (clause 7.1.2), organizational values, and existing processes. Externally, the organization must take into account the evolving regulatory landscape governing healthcare delivery, advancements in medical technology, patient expectations, and broader socioeconomic conditions. This dual assessment provides the foundation upon which all subsequent quality management activities are built, ensuring that the system is designed to respond effectively to the specific challenges and opportunities of the healthcare environment.

Closely linked to this contextual analysis is the requirement set out in clause 4.2, which calls for the identification and ongoing monitoring of all interested parties whose needs and expectations may have a significant impact on the QMS. In a hospital context, this encompasses a broad range of stakeholders. Patients and their families, whose primary expectation is the delivery of safe, timely, and effective care; healthcare professionals (including physicians, nurses, and allied health workers) who require clearly defined roles, adequate resources, and a supportive working environment; regulatory and accreditation bodies, which impose mandatory compliance standards; and technology and pharmaceutical suppliers, whose products and services directly impact care quality. The organization must continuously monitor and review the requirements of these stakeholders, as they may evolve over time in response to changes in legislation, medical knowledge, or patient expectations.

Once the organizational context and stakeholder needs have been assessed, clause 4.3 requires the organization to define the scope of its QMS. This involves determining which services, departments, and processes fall within the boundaries of the system, taking into consideration the internal and external factors identified under clause 4.1, the stakeholder requirements identified under clause 4.2, and the full range of services offered by the hospital. A hospital must take into account its internal and external factors, the requirements of relevant interested parties, and the full range of services it provides: such as emergency care, surgical units, diagnostic services, or outpatient clinics.

Where certain requirements of the standard are deemed not applicable, the organization must provide a justified explanation, provided that such exclusions do not affect its ability to ensure the conformity of its services or enhance patient satisfaction

The final element of this section, addressed in clause 4.4 concerns the establishment and ongoing management of the QMS and its constituent processes. The hospital must identify all processes necessary for the effective functioning of the system, define their sequence and interactions, and ensure that appropriate criteria, methods, and performance indicators are in place to monitor and control them. Responsibilities and authorities must be clearly assigned, and sufficient resources must be allocated to support process execution. Furthermore, the organization must proactively address the risks and opportunities identified during the planning phase, in accordance with clause 6.1, in order to prevent undesired outcomes and drive continual improvement. The maintenance of documented information, both to support process operation and to provide evidence of conformity, represents a further obligation under clause 4.4.2, ensuring transparency and accountability throughout the system. In this way, the QMS becomes an integrated operational framework, ensuring that every aspect of hospital activity is oriented toward consistent delivery of high-quality care and the continuous enhancement of patient satisfaction.[33]

3.3.5 Leadership

Effective leadership represents one of the fundamental pillars of a Quality Management System, and clause 5.1.1 of ISO 9001:2015 places explicit responsibility on top management to demonstrate visible and active commitment to the QMS. In a healthcare context, this translates into a series of concrete obligations: taking the responsibility for the effectiveness of the quality management system, ensuring that the quality policy and objectives are established and consistent with the context and strategic direction of the institution, integrating quality requirements into the core business processes of the organization, promoting a culture that values the process approach and risk-based thinking and guarantee the availability of the resources necessary for achieves the expected results for the quality management system, providing support to all the people that contribute to the effectiveness of this system, showing leadership to their respective areas of responsibility.

The concept of customer focus (clause 5.1.2) takes on particular significance in the healthcare context, where failure to meet users' needs can have a direct impact on patients' health and well-being. Senior management is responsible for ensuring that the needs of patients and their families are consistently identified, understood and met. This involves understanding both the clinical aspects of care (such as diagnostic accuracy, therapeutic effectiveness and patient safety) and the relational and experiential aspects of the healthcare encounter, including respectful communication, emotional support and timely access to services. Leadership must be able to gather patient feedback, enabling it to monitor satisfaction levels and translate these into tangible improvements in service delivery. At the same time, it must remain alert to the risks and opportunities that may arise from changes in patient expectations, regulatory requirements or the wider healthcare context, ensuring that the organisation is always able to respond effectively.

The establishment of a quality policy (clause 5.2.1) is one of the most evident expressions of management's commitment to quality. Rather than being a generic statement of intent, a healthcare organisation's quality policy should serve as a meaningful strategic document that clearly expresses the organisation's commitment to patient safety, regulatory compliance and the continuous improvement of standards of care. The framework provided must be coherent, but above all it must contain specific and measurable quality objectives across all departments. However, the value of a quality policy depends entirely on its effective communication and practical implementation throughout the organisation. Hospital management must therefore commit to ensuring that every member of staff, regardless of their role or length of service, understands the policy, recognises its relevance to their day-to-day work and feels able to contribute to its implementation. Where appropriate, the policy should also be made accessible to external stakeholders, thereby reinforcing the institution's public accountability for the quality of the care it provides.

The final aspect of leadership covered in this section concerns the allocation of roles, responsibilities and authority within the organisation (clause 5.3). In the inherently complex and multidisciplinary environment of a hospital, where clinical, administrative and support functions must operate in close coordination, a clear and well-communicated structure of responsibility is essential. Senior management must appoint specific individuals with the authority and responsibility to oversee

compliance with the Quality Management System (QMS), monitor process performance, report quality-related results to senior management and promote patient-centred values across all areas of the organisation. Equally important is the need to safeguard the integrity of the QMS during periods of organisational change, ensuring that changes to staffing, structure or operational processes do not compromise the continuity or effectiveness of quality management activities. When roles and responsibilities are clearly defined and genuinely understood, the conditions are created for a cohesive, accountable and improvement-oriented healthcare organisation, in which quality and patient safety are embedded as shared institutional values.[33]

3.3.6 Planning

A key stage in implementing a Quality Management System is planning, as this translates the organisation's strategic intentions into concrete and actionable measures aimed at ensuring consistent quality outcomes. Specifically, clause 6.1 of the ISO 9001:2015 standard requires organisations to map out in advance the risks and opportunities that need to be addressed in order to ensure that the QMS can achieve its intended results, maximising benefits and minimising undesirable outcomes, thereby promoting continuous improvement. In the healthcare sector, this risk-based approach is particularly important, given that organisational shortcomings have a direct impact on patient safety and well-being. Clinical risks are numerous and varied, and include treatment errors, misdiagnoses, healthcare-associated infections, surgical complications and shortcomings in the coordination of care between multidisciplinary teams. Senior management, in collaboration with clinical and administrative staff, is responsible for systematically analysing these critical issues and assessing their potential impact so that proportionate measures can be taken to mitigate them. At the same time, the planning process must pay equal attention to opportunities arising within the healthcare sector, such as the adoption of innovative medical technologies, the introduction of evidence-based clinical protocols, the development of new diagnostic capabilities or the expansion of telemedicine services. By addressing both risks and opportunities in a structured and documented manner, the hospital ensures that its QMS is not merely reactive but genuinely oriented toward proactive improvement and sustainable excellence in care delivery.

Based on the results of the risk and opportunity assessment, clause 6.2 requires the organisation to establish quality objectives within the relevant functions, levels and processes of the Quality Management System (QMS). These objectives must meet a number of specific criteria: they must be consistent with the quality policy, measurable, take into account the applicable requirements, be relevant to the conformity of products and services and to improving customer satisfaction, and be monitored, communicated and updated as appropriate. In a hospital setting, quality objectives might include reducing the rate of healthcare-associated infections below a defined threshold, decreasing average waiting times for patients in A&E departments, improving scores in patient satisfaction surveys, increasing the percentage of clinical staff who have completed mandatory safety training, or achieving full compliance with national accreditation standards. Each objective must be accompanied by a clear action plan specifying the purpose of the changes and their potential consequences, the resources that will be required, who will be responsible, the timeframe for completion, and the criteria against which the results will be assessed. This structured, goal-oriented approach enables us to set measurable commitments that can be monitored, reviewed and reported on at regular intervals.

Another important element of the planning phase concerns the management of changes to the QMS. In a dynamic healthcare environment, organisational change is inevitable: whether driven by changes in the demographic composition of patients, updates to regulatory requirements, the introduction of new medical technologies, or internal restructuring initiatives. The ISO 9001:2015 standard requires that, whenever a need to make changes to the QMS is identified, such changes must be implemented in a planned and systematic manner. The organisation must carefully assess the purpose of the proposed change and its potential consequences, the continued integrity of the QMS during and after the transition, the availability of the resources necessary to implement the change effectively, and the reallocation of responsibilities and authorities. In a hospital setting, this means that the introduction of a new electronic health record system, the reorganisation of a clinical department or the review of patient care pathways must be managed through a structured change process that minimises disruption to ongoing quality activities and ensures that the intended improvements are actually achieved. By incorporating structured change management practices into their QMS, healthcare organisations can navigate periods of transition with confidence, whilst

maintaining the continuity and effectiveness of their quality management activities throughout the process.

Beyond internal audits and management reviews, ISO 9001:2015 also requires periodic external audits conducted by accredited and independent certification bodies. Unlike internal audits, which are self-directed improvement tools, external audits provide an objective third-party verification that the quality management system genuinely conforms to the requirements of the standard and is effectively implemented in practice.
The certification process consists of two stages: an initial documentation review, in which the certification body assesses whether the QMS has been adequately designed, followed by an on-site audit, during which assessors observe processes, interview staff, and examine records to verify real-world implementation. A certificate is issued for a three-year period, with annual surveillance audits to ensure ongoing compliance and a full recertification audit at the end of the cycle.
In a healthcare setting, the value of external audit goes beyond the formal attainment of a certificate. It provides an independent and credible quality signal to patients, referring clinicians, and institutional stakeholders, and introduces external benchmarks and perspectives that enrich the organisation's own improvement efforts. Perhaps most importantly, the discipline required to prepare for and maintain certification, documenting processes, training staff, tracking non-conformities, and closing corrective actions, sustains a culture of quality over time, ensuring that improvement remains a continuous organisational commitment rather than a periodic exercise.[33]

3.3.7 Support

The effective implementation of a Quality Management System depends not only on sound planning and strong leadership, but also on the availability and proper management of all the resources necessary to support its operation. Clause 7.1 of the standard stipulates that the organisation must determine and provide the resources necessary for the establishment, implementation, maintenance and continuous improvement of the QMS, considering both the capabilities and limitations of existing internal resources and the potential contribution of external suppliers.
The physical infrastructure (clause 7.1.3) encompasses not only clinical buildings and facilities, but also the full range of medical equipment, diagnostic technologies, hardware, software and communication systems on which the safe and effective delivery of care depends. The organisation

must ensure that this infrastructure is not only adequate in scope but is also properly maintained, regularly reviewed and updated in response to evolving clinical needs and technological advances. Equally important is the working environment, as set out in clause 7.1.4, which must support the physical and psychological wellbeing of healthcare professionals by fostering conditions that encourage concentration, precision and collaborative practice, all essential elements in a high-risk clinical setting. This is because one of the most important resources of any healthcare organisation is its staff, and clause 7.1.2 requires the hospital to identify and provide the staff necessary for the effective operation of the Quality Management System (QMS) and the control of its processes. However, it is not enough simply to have a sufficient number of staff; these staff must be competent, having received appropriate education, training and experience. In a hospital, this translates into a systematic and ongoing commitment to training medical staff through refresher courses on evidence-based practices, patient safety protocols, infection control procedures and the correct use of medical equipment, whilst administrative staff must be equipped with the knowledge and skills necessary to effectively manage documentation, data and quality reporting processes. Where skills gaps are identified, the organisation must take prompt action to address them, either through more targeted training programmes or by recruiting additional qualified staff. Furthermore, it is essential to maintain documented evidence of the skills acquired. This investment in human capital is not only a regulatory obligation but a fundamental prerequisite for the provision of safe, consistent and high-quality patient care. In addition to the competence requirements, clause 7.3 stipulates that all personnel working under the organisation's control must be aware of the quality policy, the relevant quality objectives, their individual contribution to the effectiveness of the Quality Management System (QMS) and the implications of non-compliance with its requirements. In a healthcare organisation, given the direct relationship between staff and patients, fostering this awareness is particularly important.

Every member of staff, from the most senior consultant to frontline support staff, must understand how their role contributes to the wider mission of providing safe, high-quality care, and must feel personally responsible for meeting the standards that the QMS is designed to ensure. This sense of shared responsibility is reinforced by the communication requirements set out in clause 7.4, which oblige the organisation to determine what needs to be communicated, to whom, through which channels and how frequently. In a hospital setting, effective communication between clinical and administrative teams is essential for preventing errors, coordinating care pathways and ensuring

that quality-related information reaches those who need it in a timely and accessible manner. Regular team briefings, cross-departmental meetings, digital communication platforms and clearly defined reporting lines are all important mechanisms through which a culture of open, transparent and quality-focused communication can be fostered.

The standard requires the organisation to retain the documented information necessary for the operation of the Quality Management System (QMS) and to keep it as evidence that processes are carried out as planned. In the healthcare sector, the proper management of clinical and administrative documentation is of fundamental importance, as it underpins both the continuity of patient care and the organisation's ability to demonstrate compliance with regulatory and accreditation requirements. The entire lifecycle of documents (from creation to retention) must be managed securely. Before use, every document must be verified and approved; it must then be protected against any unauthorised alterations, whilst ensuring it remains accessible to anyone who needs it. In an environment where medical records, treatment protocols, audit reports and regulatory documents must be managed with precision and accountability, a well-designed document control system is not merely a procedural formality, but an essential safeguard for patient safety and the integrity of the organisation.[33]

3.3.8 Operation

The operational aspect of a Quality Management System represents the stage at which strategic planning and organisational commitments are translated into the specific processes through which products and services are provided to customers. Clause 8.1 requires the organisation to plan, implement and monitor the processes necessary to meet the requirements relating to the provision of products and services, as well as to implement the actions established during the planning stage. In a hospital setting, this obligation covers the entire clinical care pathway, from the initial assessment of the patient and triage through to diagnosis, treatment planning, therapeutic intervention, discharge and post-discharge follow-up. Each of these stages must be governed by clearly defined criteria, supported by adequate resources and subject to systematic monitoring and control to ensure that care is provided in a consistent and safe manner, in compliance with both regulatory requirements and patients' expectations. Any changes must be managed in a controlled manner, assessing their consequences – particularly in the case of unintended changes – and taking

measures to mitigate any adverse effects. The hospital must also monitor services outsourced to external providers.

A fundamental prerequisite for effective operational control is a thorough understanding of the requirements of the services to be provided. In this context, clause 8.2 establishes a structured framework for identifying, reviewing, and managing customer needs throughout the service period. If we apply this principle to the healthcare sector, the first step is to create effective and clear communication with patients and their families, as required by clause 8.2.1, which includes providing clear information about available services, managing appointments and care requests, collecting patient feedback and complaints, and defining specific requirements for emergencies. Before committing to providing care, the organization must carefully examine patients' needs, as indicated in clause 8.2.3, ensuring it has the capacity and skills to meet them. It's important to consider not only the implicit requirements related to the use of services, applicable regulatory obligations, and any organizational requirements set by the hospital itself, but above all the needs expressed by the patient. When requirements change during treatment (clause 8.2.4), it's crucial to update the staff involved, ensuring continuity and consistency in care.

According to clause 8.3, the hospital must establish and maintain a design and development process suitable to ensure the subsequent delivery of its services, carefully planning the development stages, assigning responsibilities, defining verification and validation activities, and managing the interfaces between the different groups involved. Design inputs must be structured to include functional and performance requirements, applicable regulatory standards, and lessons learned from previous experiences, while design outputs must adhere to these inputs and be validated to confirm that the resulting services meet patient needs in real clinical conditions. To prevent negative impacts on services, any changes made during or after the design process must be reviewed.

Since hospitals are organizations that regularly rely on a network of external suppliers and service providers, special attention needs to be paid to clause 8.4, which governs this management. The hospital needs suppliers of medical devices, pharmaceuticals, laboratory services, sterilization facilities, catering and cleaning contractors, and specialized clinical service providers. Equally important is the evaluation, selection, and monitoring of these external suppliers, based on their ability to provide processes, products, and services that meet the hospital's needs. First of all, clear

and complete information must be communicated to external suppliers regarding the services and products to be provided, along with the applicable approval requirements, the expected competency standards for their staff, and the monitoring and verification activities that the hospital plans to carry out at their sites. The level of control applied should be proportional to the potential impact of the externally provided elements on the hospital's ability to consistently meet patient requirements and regulatory obligations.

Clause 8.5 deals with the production and service delivery requirements that govern the daily provision of clinical care, which must take place under strictly controlled conditions, ensuring that the documented information clearly shows the service characteristics and the expected outcomes. To achieve this, the hospital is required to use resources suitable for monitoring and measurement, carry out verification activities at relevant stages to meet acceptance criteria, and maintain proper infrastructure and work environments managed by qualified and competent staff. Identification and traceability, covered by clause 8.5.2, are a key part that allows monitoring a patient's care status at any time. The organization also needs to pay proper attention to any property belonging to patients or external suppliers that is under its control, including personal belongings, medical records, biological samples, or implantable devices, and should promptly inform the relevant party of any loss, damage, or deficiency found, as specified in clause 8.5.3.

The final part of the operational phase deals with controlling nonconforming results, as outlined in clause 8.7. In a healthcare setting, nonconformities can show up in different ways, including medication errors, incorrect diagnoses, failure to follow established clinical protocols, treatment delays, or adverse events for patients. It's up to the organization to make sure that results that don't meet requirements are identified to prevent their use and controlled before delivery. If a nonconformity is found, it's the hospital's job to take action based on the nature of the deviation and its potential impact on patient safety, which could include correcting the mistake, segregating or containing the nonconforming result, notifying the patient or relevant clinical staff, or requesting authorized concessions where applicable. Once corrective action has been taken, compliance with the requirements must be checked again. Any non-compliance should be accurately documented, including a description of the nature of the deviation, the actions taken, any approvals obtained, and the identity of the authority responsible for deciding the course of action. This systematic

approach to managing non-compliance not only protects patients from immediate harm, but also creates the organizational learning needed to prevent recurrence and continuously improve the quality and safety of care.[33]

3.3.9 Performance Evaluation

Systematic performance evaluation is an essential part of any effective Quality Management System, giving an organization the evidence it needs to see how well quality objectives have been met and to pinpoint areas that need corrective action or further improvement. Clause 9.1.1 sets out the basic requirements for proper monitoring, measurement, analysis, and evaluation, asking the organization to figure out what needs to be monitored and measured, specify the methods for generating valid and reliable results, and indicate how often monitoring activities should be carried out. In a healthcare setting, this means setting up a system of clinical and quality indicators that can capture the multidimensional nature of hospital performance. These indicators can include patient wait times in emergency departments and outpatient clinics, rates of hospital-acquired infections, surgical complications and readmission rates, frequency of treatment errors, adherence rates to established clinical protocols, staff-to-patient ratios, and the timeliness of diagnostic reports. When these indicators are constantly analyzed and monitored, they allow hospital management to have an accurate and dynamic picture of organizational performance, enabling timely interventions if standards are not met.

Clause 9.1.2 deals with measuring patient satisfaction. The hospital is required to monitor patients' perceptions based on their needs and expectations. Patient satisfaction surveys, structured feedback mechanisms at discharge, formal complaint management systems, discussion groups with patient representatives, and online review analysis are all valuable tools through which the hospital can gather patients' perspectives on the quality and humanity of the care they received. The information collected from all these processes should be treated as a key input in the organization's quality improvement processes, influencing decisions on service redesign, staff training priorities, and communication practices. Clause 9.1.3 also requires the organization to analyze and evaluate the data gathered from information collection, using the results to assess service compliance, patient satisfaction levels, QMS effectiveness, the success of planning activities, supplier

performance, and the need for further improvements. Statistical techniques and data visualization tools can be used to support this analytical process, allowing management to spot trends, identify emerging risks, and confidently prioritize improvement initiatives.

According to clause 9.2, the hospital must conduct internal audits at planned intervals, taking into account changes that affect the organization and the results of previous audits. In a healthcare context, internal audits can cover a wide range of areas, including the compliance of clinical departments with documented care protocols, the effectiveness of infection control measures, the accuracy and completeness of clinical documentation, the adequacy of staff training records, and the proper management of medical equipment and supplies. Auditors should be selected to ensure objectivity and impartiality, which means that people should not audit their own work or areas for which they have direct operational responsibility. Any non-conformities must be reported immediately to ensure timely resolution. All audit activities, results, and follow-up actions should be kept as documented information, providing a traceable record of commitment to continuous improvement.

Management review, required under clause 9.3, represents the highest-level mechanism through which top management fulfils its responsibility to oversee and direct the QMS. QMS reviews are conducted at planned intervals to ensure its ongoing suitability, adequacy, effectiveness, and alignment with the organization's strategic direction. The inputs for this review are deliberately comprehensive, including the status of actions from previous management reviews, changes in external and internal factors relevant to the QMS, performance data and trends related to patient satisfaction and stakeholder feedback, the degree of achievement of quality objectives, process performance and service compliance indicators, results of non-conformities and corrective actions, results of monitoring and measurement, outcomes of internal audits, the performance of external suppliers, the adequacy of available resources, and the effectiveness of actions taken to address risks and opportunities. The review should consider both the opinions of patients and healthcare workers, and everything has to be documented as proof that it was done.[33]

3.3.10 Improvement

The main goal of the Quality Management System is the pursuit of continuous improvement, and it is governed by the ISO 9001:2015 standard. Clause 10.1 states that the organization must identify and select improvement opportunities and implement all necessary actions to meet customer requirements and increase customer satisfaction. In a healthcare context, this commitment to improvement is not just an organizational aspiration, but a moral and professional imperative, since the consequences of stagnation or complacency can directly affect the health, safety, and well-being of patients. Improvement activities in a hospital setting can take many forms, ranging from small tweaks to established clinical protocols and administrative workflows, all the way to more fundamental changes in how care is organized and delivered. Every improvement initiative should be pursued systematically, documented, and rigorously evaluated, which is key if you want to achieve real benefits for both patients and the hospital as a whole.

When a non-conformity occurs, whether it's identified through a patient complaint, an adverse clinical event, an internal audit result, or routine process monitoring, according to clause 10.2, the organization should respond in a structured and timely way. The immediate response should focus on containing the non-conformity, correcting the deviation where possible, and managing the consequences for the people involved. In a hospital setting, this could mean pulling a mistakenly prescribed drug, reviewing a care plan that didn't meet established clinical standards, or providing extra support to a patient who had an adverse event. However, the requirements of clause 10.2 go well beyond just immediate correction, as it's also necessary to understand the root causes of nonconformity, assess whether similar problems exist or could arise in other parts of the system, and determine what corrective actions are needed to eliminate the underlying causes and prevent the issue from happening again. This kind of analysis is crucial in healthcare settings, where any adverse event affects patient health, often due to poor communication between clinical teams, inadequate staff training, or poorly designed care processes, rather than isolated mistakes by individuals. Every corrective action should match the seriousness and potential impact of the non-compliance, and its effectiveness needs to be checked after a set period to make sure the problem has been fixed and no unintended consequences have popped up. Every step of this process, from spotting the issue in the first place to checking the results, should be documented and recorded to make sure the same mistake isn't made again.

Clause 10.3 requires the organization to continuously improve the suitability, adequacy, and effectiveness of its quality management system, using the results of analysis and evaluation activities and the outputs of management reviews to identify needs and opportunities that should be included in the improvement agenda. In a healthcare organization, continuous improvement shows up on multiple levels at the same time. On the clinical side, it means constantly fine-tuning diagnostic and treatment practices in line with evolving medical evidence, reducing preventable harm through enhanced safety protocols, and progressively improving patient outcomes measured through clinical performance indicators. On an organizational level, it involves simplifying administrative processes, eliminating inefficiencies in resource allocation, strengthening communication and coordination between departments, and developing a workforce that is increasingly skilled, engaged, and quality-conscious. On a cultural level, perhaps even more importantly, continuous improvement requires fostering a mindset where every staff member (regardless of role or seniority) views identifying and reporting problems not as a cause for blame, but as a valuable contribution to the collective effort to provide safer, more effective, and compassionate care. When this culture of improvement is truly rooted throughout the organization, the QMS stops being just a compliance mechanism and instead becomes a living system through which the hospital learns, adapts, and continuously moves forward in its mission to provide the highest possible standard.[33]

4. RESULTS

4.1 Analysis of Context - SWOT Analysis

A SWOT analysis was conducted to identify the internal strengths and weaknesses of the SCDU of Dermatology and Venereology, as well as the external opportunities and threats, in accordance with the context analysis required by ISO 9001:2015.

STRENGTHS **INTERNAL · POSITIVE**	**OPPORTUNITIES** **EXTERNAL · POSITIVE**
Formalised clinical pathways (PDTA) and internal procedures based on updated guidelines	Strengthening multidisciplinary collaboration with other professionals involved in patient care
Specialised techniques: Mohs micrographic surgery, sentinel lymph node biopsy, phototherapy	Increasing participation in clinical trials, including studies with pre-approval drugs
Medical staff specialised in moderate-to-severe psoriasis, severe atopic dermatitis, melanoma, and NMSC	Activation of the institutional telemedicine platform for second-level outpatient clinics
Residency Training School in Dermatology and Venereology (University of Eastern Piedmont)	Access to a faster Pharmacy service for the supply of induction therapy drugs
Paediatric Dermatology clinic with staff holding a specific postgraduate qualification	
Dedicated Data Manager for clinical trial and departmental data management	
Centralised alarm system for monitoring the temperature of biological/investigational drug refrigerators	
Videodermoscope available at the melanoma clinic	
Centre attractiveness documented by inward patient mobility to second-level clinics	
Effective multidisciplinary teamwork with specialist consultants	
IT system for viewing laboratory, instrumental, and histopathological results	
Periodic checks on the suitability of facilities and electromedical equipment	

WEAKNESSES INTERNAL · NEGATIVE	THREATS EXTERNAL · NEGATIVE
Inadequate nursing resources for first-level outpatient clinics at both sites (Novara and Galliate)	Non-conformities leading to adverse events for patients
High volume of non-medical administrative tasks carried out by medical staff, reducing time available for clinical activity	Failure to meet deadlines set by clinical study protocols
Suspension of the phototherapy service due to equipment failure	Cardiac adverse events in the operating room due to the daily absence of an anaesthesiologist
Loss of Day Hospital surgical slots due to missed cancellations, leading to longer waiting lists	Growing inflow of patients from other regions increasing the overall workload
Difficulties managing surgical Day Hospital bookings across two separate sites	Incorrect management of AIFA treatment plans by local pharmacies, risking interruption of drug coverage
Challenges in migrating patient records to the new outpatient reporting system	Reduction in research funding from pharmaceutical companies and public institutions
Anaesthesiologist presence in the operating room reduced to one day per week	
Digital signature malfunctions preventing validation of medical reports	
Inadequate use of visit validation systems	

Table 3: SWOT analysis of the SCDU of Dermatology and Venereology (Year 2025)

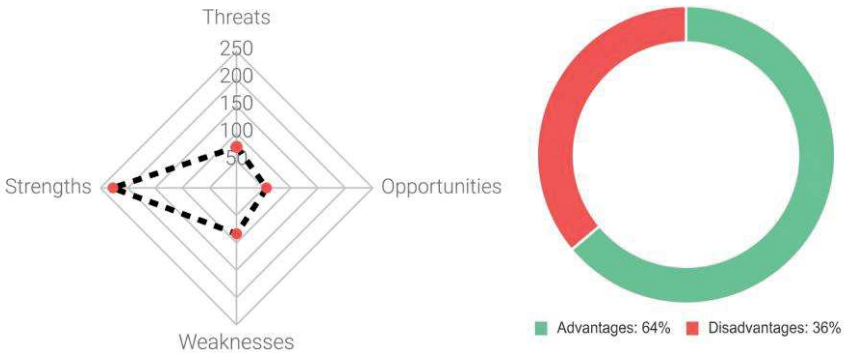
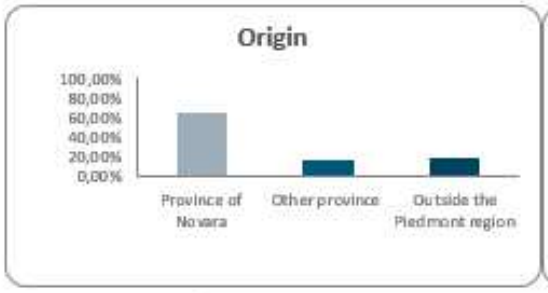
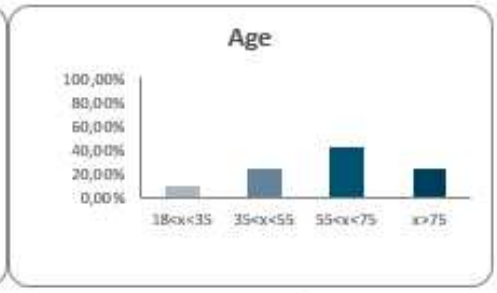


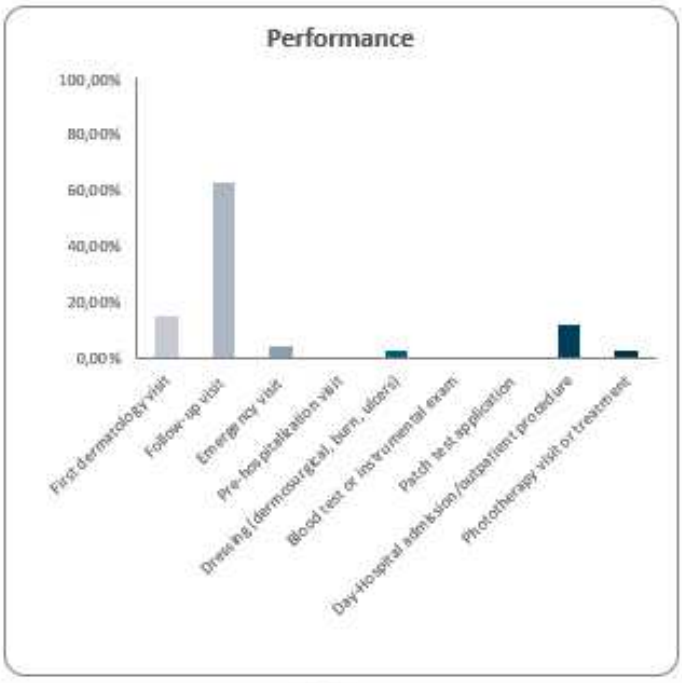
Figure 2: Radar chart and summary distribution of the SWOT analysis of the SCDU of Dermatology and Venereology. The radar chart illustrates the relative weight of each dimension, while the pie chart shows the overall balance between advantages (strengths and opportunities, 64%) and disadvantages (weaknesses and threats, 36%).

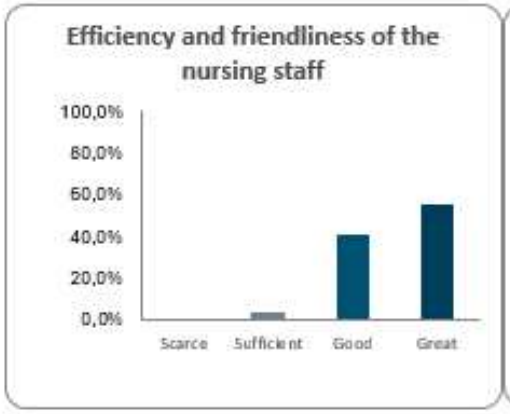
4.2 Patient and Staff Satisfaction

In accordance with the ISO 9001:2015 Quality Management System requirements, the satisfaction of both patients and staff was evaluated through the administration of dedicated questionnaires.









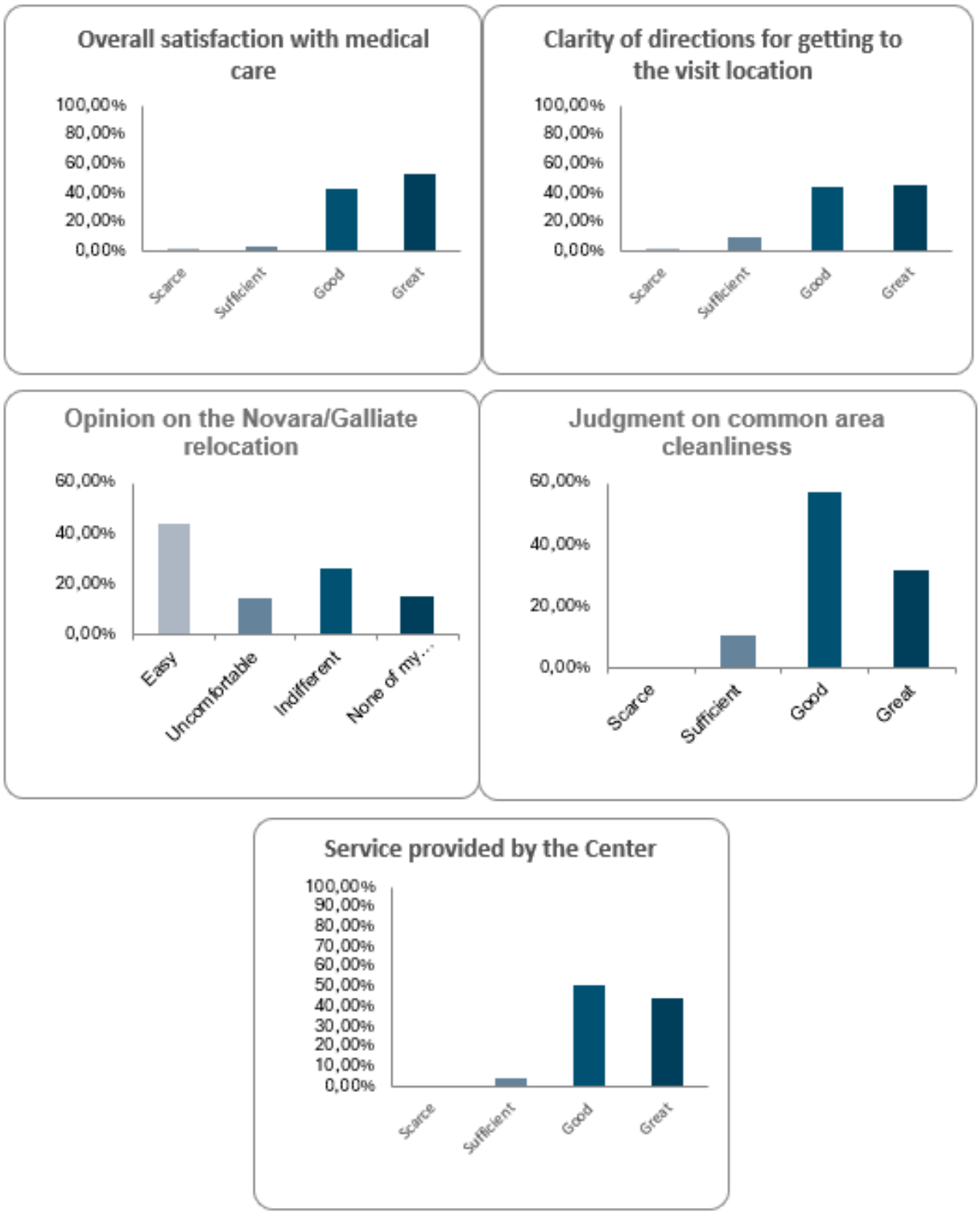


Figure 3: Patients satisfaction questionnaire results (Year 2025)

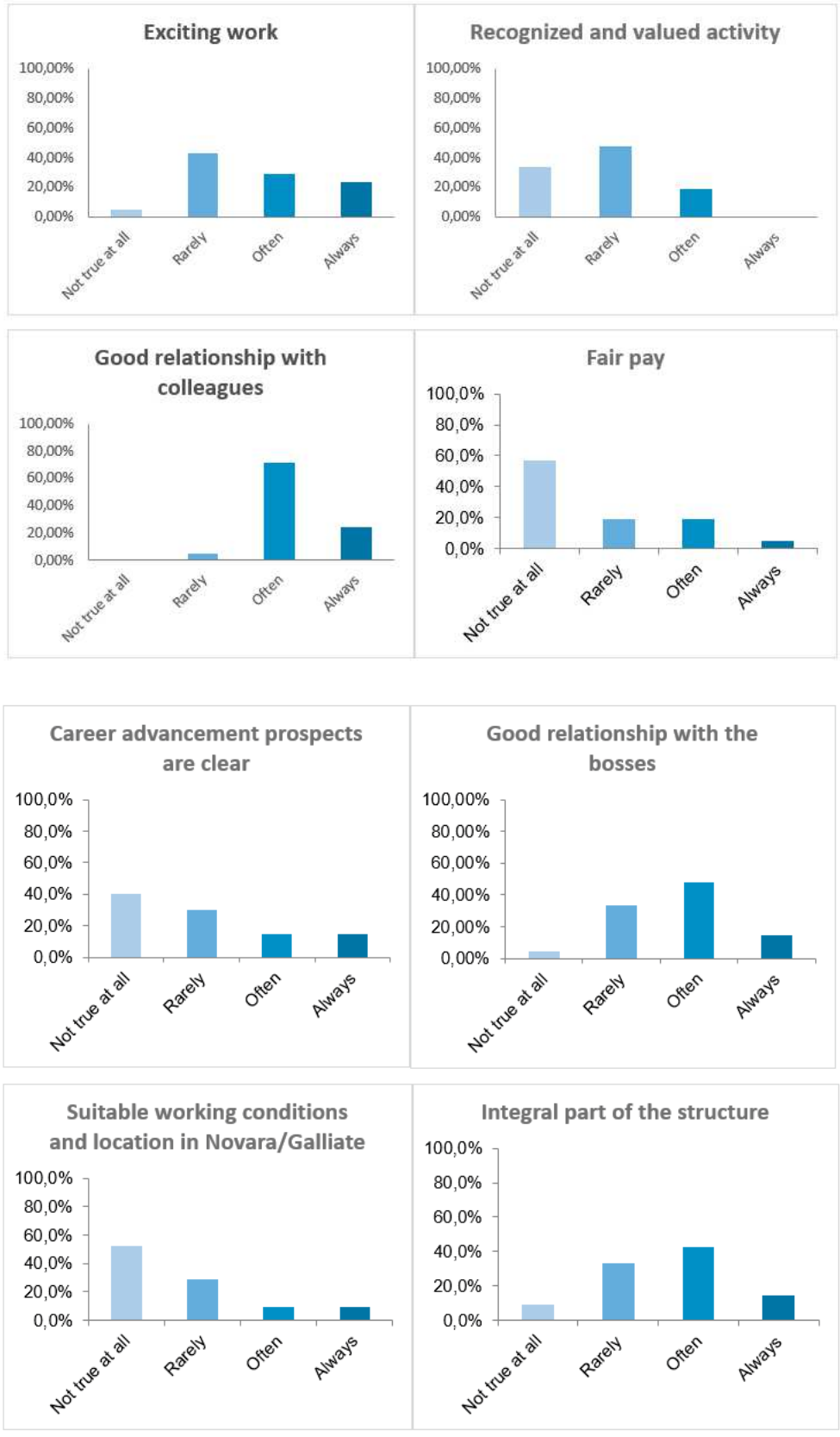


Figure 4: Staff satisfaction questionnaire results (Year 20205)

4.3 Key Performance Indicators (KPIs)

The performance of the SCDU of Dermatology and Venereology was monitored through a set of indicators covering clinical activity, waiting times, and quality of care. The data collected for the years 2023, 2024, and 2025 are reported below for each area of excellence.

4.3.1 Dermosurgery – Mohs Micrographic Surgery

In order to monitor the activities carried out, two main indicators are recorded annually: the number of procedures performed using the direct Mohs technique and the number of procedures performed using the delayed Mohs technique.

In the three-year period 2023–2025, the data show a variable trend. Procedures with the direct technique saw a gradual decrease, going from 46 cases in 2023 to 41 in 2024, and down to 34 in 2025. The delayed technique, on the other hand, peaked in 2024 with 156 cases compared to 84 in 2023, followed by a partial drop to 117 in 2025, which still remains significantly higher than the starting figure.

Overall, the volume of surgical activity using the Mohs technique remains significant over the period considered, with a trend showing an increase in the delayed technique compared to the direct one, which might reflect an evolution in clinical indications and organizational methods in the department.

4.3.1.1 Accessibility and Waiting Times

Access to dermosurgery procedures takes place through internal booking following an outpatient dermatological assessment. To monitor accessibility to services, waiting times for the different types of procedures are recorded annually.

In the three-year period 2023–2025, the data show different trends depending on the type of access. For outpatient scheduled procedures, there is a gradual increase in waiting times, going from 35 days in 2023 to 39 days in 2024, up to 49 days in 2025. Similarly, scheduled Day-Hospital procedures saw a decrease in 2024, with a 38-day wait compared to 54 days in 2023, followed by a new rise to 46 days in 2025.

Regarding Mohs surgery procedures, the waiting times for the direct technique showed a sharp drop in 2024, going from 65 days in 2023 to 14 days, and then rising again to 40 days in 2025. The waiting times for the delayed technique, on the other hand, were more stable, decreasing from 54 days in 2023 to 38 in 2024, with a slight increase to 46 days in 2025. Overall, despite some fluctuations, waiting times remain within a range compatible with planned surgical activity, with room for improvement still achievable, particularly for outpatient access.

4.3.2 Melanoma Unit

To monitor the activity carried out in the diagnosis and management of melanoma and other skin cancers, several indicators are recorded annually: the number of new melanoma diagnoses, the number of new non-melanoma skin cancer (NMSC) diagnoses, and the number of multidisciplinary oncological assessments performed. As with any measured indicator, a comparison over the last three years is then conducted. Over the three-year period, new melanoma diagnoses show a declining trend, falling from 33 cases in 2023 to 26 in 2024 and 24 in 2025. This trend may reflect a variation in detected incidence or in the referral patterns of patients to the center. In contrast, new NMSC diagnoses show a steadily increasing trend, rising from 915 cases in 2023 to 1218 in 2024 and 1241 in 2025, a finding that may reflect both an expansion of diagnostic activity and a growing awareness among the population regarding cutaneous neoplastic conditions.

Multidisciplinary oncological assessments also show a constantly growing trend, increasing from 1130 in 2023 to 1150 in 2024 and 1165 in 2025. This data reflects a progressive strengthening of the collegial and interdisciplinary approach to the management of oncological patients, in line with the principles of integrated care promoted by national and international guidelines.

4.3.2.1 Accessibility and Waiting Times

For patients who are already being cared for, there aren't really any strict waiting times: regular follow-up visits are scheduled according to guideline recommendations, based on the stage of the disease and how much time has passed since the initial diagnosis. For new appointments at the Familial Melanoma clinic, the wait for the first visit is between 4 and 6 weeks.

4.3.3 Phototherapy and Photodynamic activity

Over the past three years, activities related to phototherapy and photodynamic therapy, two important specialized treatments in dermatology, have been monitored.

As for phototherapy, in 2024, 30 patients were treated, totaling around 500 visits. In 2025, the activity dropped significantly, with only 4 patients treated with partial UV until April 22, 2025, due to a temporary suspension of the service. The activity is expected to resume during 2026. Regarding photodynamic therapy, on the other hand, there is a positive and growing trend: treatments provided went from 80 in 2024 to 104 in 2025, showing increased use of this technique within the unit.

4.3.3.1 Accessibility and Waiting Times

Patients can access the phototherapy and photodynamic therapy service after an initial dermatology visit, aimed at assessing whether the treatment is appropriate. For phototherapy, the waiting time to start

treatment cannot currently be estimated due to the temporary suspension of the service with the full-body and partial hand UVA booths. The waiting time for photodynamic therapy (PDT) is currently 1-2 months.

4.3.4 Cutaneous Lymphomas

The joint clinic dedicated to Cutaneous Lymphomas has been operating since December 2024. Since it's a recently established service, the available data only cover a limited time period. The clinic provides about 20 outpatient visits per month, a figure that shows a decent volume of activity right from the first months, confirming the clinical importance of this service within the operational unit.

4.3.4.1 Accessibility and Waiting Times

Access to the Cutaneous Lymphoma clinic happens at the time of the histological diagnosis of cutaneous lymphoma, so there are no waiting times for the patient to be taken in. Periodic follow-up visits and those during active treatment are scheduled individually, based on the stage and type of the disease, following the current guideline recommendations.

4.3.5 Inflammatory Skin Diseases

In order to monitor the activity in managing inflammatory skin diseases, indicators are recorded annually related both to the number of patients under care and the clinical effectiveness of the treatments provided, with particular focus on psoriasis and atopic dermatitis. For new patients, there's an overall upward trend: new patients under care for psoriasis went from 31 in 2023 to 44 in 2024, reaching 46 in 2025, while those for atopic dermatitis increased from 33 in 2023 to 38 in 2024, with a slight drop to 37 in 2025. The clinical effectiveness of psoriasis treatments is measured using the PASI (Psoriasis Area and Severity Index), an index that evaluates the extent and severity of skin lesions. Treatment response thresholds are recorded 16 weeks after the start of therapy, in line with the standards used in international clinical studies: PASI 75 indicates a 75% reduction in disease severity compared to baseline, PASI 90 a 90% reduction, and PASI 100 complete remission. The data from the three-year period show positive results: the percentage of patients achieving PASI 75 increased significantly, going from 20% in 2023 to 71.43% in 2024, with a slight drop to 67.7% in 2025. The percentage of PASI 90 grew from 13% in 2023 to 64.29% in 2024, settling at 60.5% in 2025. The percentage of PASI 100 stayed high, moving from 53% in 2023 to 54.7% in 2024, with a decrease to 47.1% in 2025. For atopic dermatitis, effectiveness is measured through the EASI (Eczema Area and Severity Index), an index similar to PASI but specific for eczema: EASI 50 indicates a 50% reduction in disease severity, while EASI 75 indicates a 75% reduction. Here too, the results are satisfactory: the percentage of patients with a 50% reduction in EASI remained very high, going from 100% in 2023 to 89.19% in 2024 and 87% in 2025. The EASI 75 percentage saw a drop from 80% in 2023 to 56.67% in 2024, with a partial recovery to 65.2% in 2025. Overall, the data show an increase in the number of patients treated and positive clinical results, with treatment response rates remaining at satisfactory levels over the three-year period considered.

4.3.5.1 Accessibility and Waiting Times

Access to the second-level clinic for inflammatory skin diseases is done either by directly booking from the first-level clinic or by request from other specialists, after a collegial discussion of the clinical case. This way of accessing ensures a structured and appropriate pathway, making sure that patients referred to the second level have been previously evaluated and selected based on clinical complexity.

4.3.6 Skin Conditions in Pediatric Age

The clinic dedicated to skin conditions in pediatric patients has been operating since October 2024. Since this is a newly established service, the available data still covers a limited period. The clinic runs 4 times a month, providing around 50 outpatient visits per month, a volume that shows there has been significant demand right from the first months, confirming the clinical and care importance of this service within the operational unit.

4.3.6.1 Accessibility and Waiting Times

Access to the second-level clinic for skin conditions in children happens either through direct booking from the first-level clinic or at the request of pediatric specialists, after a joint discussion of the clinical case. This approach ensures a structured and appropriate access path, making sure that patients referred to the second level have been previously evaluated based on clinical complexity and the specific needs of the pediatric age.

4.3.7 Patients Affected by Sexually Transmitted Infections

The clinic dedicated to sexually transmitted infections has seen significant changes over the years, both in the number of visits and in how it's organized. In the years before 2020, the clinic had about 120 new patients each year through walk-ins without appointments, totaling around 500-600 visits annually, including follow-ups.

In 2024, there were a total of 270 visits, a decrease compared to previous years, due to the change in access rules that removed the option of walking in without an appointment. In 2025, there’s a rebound with a total of 296 visits, suggesting that patients are gradually adapting to the new system and the clinic is recovering its activity volume.

4.3.7.1 Accessibility and Waiting Times

Access to the second-level clinic for sexually transmitted infections currently happens either through direct booking from the first-level clinic or at the request of other specialists or local doctors. This method ensures an organized and appropriate access path, making sure patients are correctly selected based on clinical complexity and the need for further diagnostic or therapeutic investigation.

4.3.8 Skin Oncology

The clinic dedicated to skin oncology currently follows over 300 organ transplant patients, including those who have had kidney, kidney-pancreas, liver, heart, and lung transplants—a group especially at risk for developing skin cancers due to long-term immunosuppressive therapy. At the same time, there are currently 10 patients being treated for locally advanced basal cell carcinoma, a condition that requires specialized and multidisciplinary clinical management.

4.3.8.1 Locally Advanced Basal Cell Carcinoma

The response rate to treatment with Hedgehog pathway inhibitors in patients with locally advanced basal cell carcinoma has consistently remained at high levels, with a historical response rate of 90% recorded in 2020. In 2023, 5 new diagnoses were recorded, with all patients still undergoing treatment at the time of evaluation. In 2024, 2 new diagnoses were made, alongside 4 re-treatments and 3 patients in follow-up; 1 patient died during the period, though from an unrelated cause. As of 2025, 10 patients are currently under care, 5 of whom were newly taken on during the year. The therapeutic response at 16 weeks was achieved by 9 out of 10 patients (90%), with only one patient treated with Sonidegib failing to reach the therapeutic target.

4.3.8.2 Electrochemotherapy

The use of electrochemotherapy in the management of cutaneous metastases and other skin tumors has shown growing activity over the three-year period. In 2023, one patient was treated for cutaneous metastases from melanoma, though lost to follow-up shortly after treatment. In 2024, 11 patients were treated, including 3 cases of squamous cell carcinoma, 6 cutaneous metastases from melanoma and 2 cases of Kaposi's sarcoma, with a response rate ranging between 70% and 90%. In 2025, 4 patients were treated with electrochemotherapy: 2 for melanoma, 1 for Kaposi's sarcoma and 1 for squamous cell carcinoma, achieving a 100% response rate at 16 weeks post-treatment.

4.3.8.3 Off-Label Therapies and Compassionate Use

The number of active off-label therapies and compassionate use treatments reflects the unit's commitment to providing access to innovative treatments for patients with complex or refractory conditions. From 2 active cases in 2023, the number rose significantly to 7 in 2024, before settling at 5 in 2025.

4.3.8.4 Accessibility and Waiting Times

The clinic dedicated to transplant patients is open every Wednesday morning, and appointments are made through the department's office, at the request of the referring transplant center. For patients with locally

advanced basal cell carcinoma, access is granted through regular booking at the first-level clinic, either at the request of the General Practitioner or after contacting specialists from nearby centers. Patients are then scheduled for the second-level clinic, where they are evaluated by the doctors in charge of the service.

4.3.8 First-Level Outpatient Activity

To monitor first-level outpatient activity, several key indicators are recorded each year: the average waiting time for the first dermatology appointment, the number of outpatient services performed, the number of Day Hospital admissions, the number of outpatient procedures, the percentage of patients coming from other ASLs in Piedmont, and the number of urgent or Fast Track visits.

The average waiting time for the first dermatology appointment is calculated based on priority classes, defined at national and regional level according to clinical urgency: class U (Urgent) requires the service to be provided within 72 hours, class B (Short) within 10 days, class D (Deferrable) within 30 days for visits and 60 days for diagnostic tests, and class P (Schedulable) within 120 days. In 2023 and 2024, the average waiting time was calculated considering classes B, D and P, standing at approximately 100 days and 76.75 days respectively. In 2025, the value returned to 100 days, this time including class U as well, since from 2025 onwards urgent visits are booked through the CUP system, while still guaranteeing the service within 72 hours of the referral. The apparent increase in average waiting time therefore does not reflect a real deterioration in accessibility, but rather a change in booking procedures.

The number of outpatient services performed peaked in 2024 with 30258 services compared to 29195 in 2023, then fell to 26996 in 2025. Day Hospital admissions show a steadily increasing trend throughout the three-year period, rising from 839 in 2023 to 876 in 2024 and 906 in 2025, reflecting a progressive expansion of this care delivery model. The number of outpatient procedures similarly peaked in 2024 with 4554 compared to 4389 in 2023, followed by a reduction to 3067 in 2025.
The percentage of patients coming from other ASLs in Piedmont shows a consistently growing trend, rising from 26.59% in 2023 to 27.7% in 2024 and up to 31.46% in 2025, reflecting a growing catchment area and the recognition of the center as a regional point of reference. Finally, urgent and Fast Track visits, recorded starting from 2024, increased from 2643 in 2024 to 2885 in 2025, highlighting a rise in the management of dermatological emergencies.

4.3.9 Clinical Research

The unit's clinical research activity is monitored annually through two main indicators: the number of patients enrolled in clinical trials and the number of active trials.

The number of enrolled patients, including both newly recruited and ongoing participants, showed a marked decrease over the three-year period. In 2023, a total of 745 patients were enrolled, a figure largely attributable to the presence of several spontaneous studies with caseloads exceeding 100 patients each. In 2024, enrollments dropped significantly to 106, as the majority of previously enrolled patients had completed their studies and no new active recruitments were underway. In 2025, the number further decreased to 97, reflecting the conclusion of several ongoing studies, partially offset by the activation of 5 new trials with active enrollment.

The number of active clinical trials remained relatively stable throughout the period, standing at 18 in 2023 and 15 in 2024, before rising to 19 in 2025, with 5 new trials opened and 6 closed during the year.

4.4 Non-Conformities and Corrective Actions

In compliance with ISO 9001:2015 requirements, non-conformities identified during internal and external audit procedures were systematically recorded and addressed through corrective and preventive actions. The analysis of non-conformities was based on data from the last three years. The staff reported a total of 26 non-conformities, spread across the following areas: operating room (16), outpatient clinic (5), equipment and logistics (2), therapy management (1), and reception/triage (2).

4.4.1 Operating Room Sector

The operating room sector represents the area with the highest number of reports. Among the non-conformities identified, particular attention goes to 4 reports of adverse events due to severe bradycardia or cardiac arrest in patients undergoing outpatient or Day Hospital procedures, which occurred following the suspension of the daily Anesthesia and Resuscitation service in the operating room. Additionally, 3 non-conformities were reported relating to electric shocks felt by both the patient and the operator during coagulation procedures, as well as 4 incidents linked to errors in accepting surgical specimens and malfunctions of the Ellipse application. Finally, a critical issue was reported concerning the excessive accumulation of histological reports awaiting delivery, attributable to delays in reporting by the Pathology department: the average reporting times have gone from 15-20 days to over 30, with the resulting risk that patients won't receive their results in time to continue the diagnostic process.

4.4.2 Outpatient Sector

The 5 non-compliances found in the outpatient sector concern different situations. One case was noted where the patient showed up for an appointment on the wrong date due to the rescheduling not being recorded. At the Galliate facility, the following were reported: the autoclave broke down, requiring surgical instruments to be sent to Novara for sterilization; a temperature alarm went off on the drug refrigerator, which was noticed on Monday morning when staff arrived because the door had been left open over the

weekend. There was also a report of active nasal mucosa bleeding that couldn't be controlled during a dermosurgical dressing on a patient who had undergone rhinectomy for squamous cell carcinoma.

4.4.3 Equipment and Logistics Sector

Non-conformities in the equipment and logistics sector include a power outage at the Galliate facility, which caused an interruption of IT services, as well as the malfunction of the ward's electrocardiograph used for Day Hospital patients.

4.4.4 Admission/Triage Department

An incident was reported where a patient was admitted to pre-hospitalization with incorrect personal data, which was promptly corrected but without reprinting the related identification labels.

4.4.5 Research Department

In the research department, there was a case of a patient missing a scheduled visit as part of a clinical trial, which could not be made up for according to the timelines set by the study protocol.

4.4.6 Non-Conformities Found During Audit

During the pharmacy audit on June 6, 2025, the following non-conformities were noted: presence of medicines in the cabinet without barcodes, failure to update the check on medicine expiration dates (last recorded check in March 2025), and the presence of an expired hydrocortisone (Flebocortid) package from May 2025, labeled but still in the cabinet.

During the internal audit on February 20, 2026, a major non-conformity was identified: despite a report already made in March 2025 regarding the absence of a 24/7 continuous temperature monitoring system for the pharmacy refrigerators at the Galliate clinic, this system had not yet been implemented. The lack of an alarm with a remote sensor led to the failure to detect a malfunction over the weekend, resulting in a break in the cold chain and disposal of the entire contents of the fridge and the need to repurchase the medications.

4.5 Staff Training and Competencies

Staff training and continuous professional development represent a core requirement of the ISO 9001:2015 Quality Management System. All healthcare professionals of the SCDU of Dermatology and Venereology are required to maintain and update their clinical and technical competencies through participation in accredited continuing medical education (CME) courses, national and international conferences, and scientific publications. To ensure continuous updating of knowledge and skills, each year every staff member is asked to plan the training activities for the following year. After a year, a comparison is made between the planned activities and those actually carried out, allowing the monitoring of compliance with individual training paths.

The training activities are divided into two main areas. The first concerns mandatory training, common to all healthcare workers regardless of their role, which includes workplace safety courses, fire safety training, and training initiatives promoted by the company management, including management objectives and general medicine courses. These activities are directly monitored by management, who checks that all staff complete them. The second area concerns specific training, which each worker plans individually based on their role and professional needs, through refresher and advanced courses aligned with the competencies required for their position. The specific training activities are then reviewed and assessed by the head of the operational unit, who ensures they align with the department's goals and the team's needs.

4.6 Improvement Projects

Each area of clinical activity within the SCDU of Dermatology and Venereology is associated with specific improvement projects, identified on the basis of performance monitoring and non-conformity analysis, in line with the continuous improvement cycle required by ISO 9001:2015.
In the area of clinical pathways and patient management, the unit plans to implement dedicated diagnostic and therapeutic pathways (PDTA) for all second-level clinics of the SCDU of Dermatology, with particular attention to the phototherapy pathway in anticipation of the service resumption. A brochure containing guidelines for the correct referral of patients in urgency classes U and B by the general practitioner to the dermatology clinic will also be developed.
Regarding phototherapy and photodynamic therapy, the resumption of the phototherapy service is planned following the purchase of a new device. Once restored, the unit aims to expand treatment availability to three sessions per week, subject to confirmation of dedicated staff availability, and to offer additional services such as phototests and photopatch tests, including in collaboration with the Allergology clinic for photoallergic and phototoxic reactions. Furthermore, an increase in the number of photodynamic therapy (PDT) sessions is planned, moving to two sessions per month. During spring and summer, Daylight-PDT will also be performed, allowing a greater number of patients to be treated and reducing waiting times for those with an indication for this treatment.
In the field of telemedicine, the unit intends to develop outpatient services deliverable remotely through telemedicine and televisit platforms, also to address delays in the issuance of treatment plans when patients fail to attend appointments or request rescheduling.
With regard to research and education, the unit plans to maintain and increase publications in national and international dermatology journals, continue participation in clinical trials including pediatric ones, and pursue educational events and participation in SIDeMaST campaigns on inflammatory and oncological skin diseases. The Data Manager contract renewal is also planned to support ongoing research activities.

In the area of multidisciplinary collaboration, the unit aims to establish a joint clinic with the SCDO of Infectious Diseases to improve the clinical management of sexually transmitted infections, raising the standard of care and expanding the scope to include HIV, antiretroviral therapy, and pre- and post-exposure prophylaxis. Additionally, the activation of a multidisciplinary clinic involving a medical geneticist and an oncologist is planned for the Familial Melanoma clinic, which is currently active with a geneticist and a dermatologist. For the cutaneous lymphoma joint clinic, the unit intends to increase collaboration with the Pathologist for definitive histological diagnosis and to initiate extracorporeal photopheresis (ECP) at the Novara Hospital.

Concerning regional and oncological networks, the Regional Technical Group for the Dermatology Area, active since the end of 2025, has planned for 2026 the definition of protocols for dose-sparing in atopic dermatitis, the management of patients affected by scabies, and the correct referral of dermatosurgical patients to reference centers. Furthermore, the Skin Tumor Study Group of the Oncological Network, of which the unit is a member, has scheduled the revision of the diagnostic and therapeutic pathways for oncological diseases, including melanoma, non-melanoma skin cancer, dermatofibrosarcoma protuberans (DFSP), Kaposi sarcoma and Merkel cell carcinoma.

Finally, with regard to staff training and quality management, the unit plans to continue mandatory training including company courses and retraining, and to maintain adherence to the staff training and development plan to ensure continuous professional updating. Efforts will also be made to improve non-conformity detection by training staff in the use of the company's non-conformity reporting form. Additionally, the unit aims to obtain nursing assistance in second-level clinics to be integrated into the clinical pathways, and to reduce waiting times for Day Hospital procedures and direct Mohs surgery.

5. DISCUSSION

The analysis presented in this paper demonstrates that the ISO 9001:2015 Quality Management System provides the SCDU of Dermatology and Venereology with a valuable and structured framework for identifying critical issues, monitoring performance, and directing improvement efforts. However, its effectiveness is ultimately contingent on the availability of adequate human and material resources, and the most significant challenges facing the unit, nursing shortages, patient safety risks in the operating room, and staff dissatisfaction share a common root in structural resource constraints that require intervention at an institutional level beyond the unit itself. The improvement objectives identified for 2026 reflect a realistic and prioritised response to these challenges, with a particular focus on the resumption of the phototherapy service, the development of telemedicine pathways, and the strengthening of multidisciplinary collaboration.

More broadly, this work aimed to describe and analyse the ISO 9001:2015 certification process undertaken by the Dermatology Department of Novara Hospital, examining the tools and methodologies adopted for implementing the quality management system, including SWOT analysis and the Plan-Do-Check-Act (PDCA) cycle, and evaluating their effectiveness in the continuous improvement of clinical and organizational processes, risk management, and stakeholder satisfaction.

The results emerging from the management review of the SCDU of Dermatology and Venereology for the year 2025 reflect the complexity of managing a highly specialised university hospital unit within a public healthcare system characterised by growing demand and limited resources.
The overall increase in activity volume, particularly in Day Hospital admissions and multidisciplinary oncological assessments, can be attributed to the progressive consolidation of second-level outpatient clinics and the growing recognition of the unit as a reference centre for the eastern quadrant of Piedmont, as confirmed by the steady rise in patients referred from outside the local health authority. The reduction in outpatient procedures recorded in 2025 should not be interpreted as a reduction in overall activity, but rather as an increase in surgical waiting times, given that these patients are subsequently referred for surgery regardless. The decline in new melanoma diagnoses over the three-year period may reflect a shift in referral patterns rather than a true reduction in incidence, as the growing complexity of cases managed, evidenced by the increasing number of multidisciplinary assessments, suggests that the unit is increasingly concentrating on higher-acuity patients. The marked increase in NMSC diagnoses, on the other hand, is consistent with the well-documented epidemiological trend of rising incidence of non-melanoma skin cancers globally, with an estimated annual rate of 2.02% from 1990 to 2021, amplified by the unit's expanding catchment area.[34] This trend is also confirmed in the European context, where, despite a slight overall decline, an increase in incidence is observed in the younger age groups in Central and Northern Europe.[35]
The strong clinical response rates observed in both psoriasis and atopic dermatitis are likely attributable to

the increasing availability and appropriate selection of biological therapies, combined with the unit's structured approach to patient monitoring through validated outcome measures such as PASI[37] and EASI[38] scores.

The concentration of non-conformities in the operating room sector is directly linked to the reduction of anaesthesiologist presence from daily coverage to one day per week, a change driven by external organisational decisions rather than by clinical choice. The adverse cardiac events recorded in this context highlight how structural resource constraints can translate into tangible patient safety risks and underscore the importance of restoring adequate anaesthesiologic support as a matter of priority. The persistence of this corrective action as "open" at the time of the review reflects the dependency of the unit on decisions made at a higher institutional level, a limitation that the quality management system alone cannot resolve. The major non-conformity identified in February 2026 regarding the drug refrigerator monitoring system is particularly significant, as it reveals a gap between the identification of a risk and its actual resolution. The fact that the same issue had been flagged nearly a year earlier without effective corrective action being implemented points to the need for stronger accountability mechanisms and clearer timelines within the corrective action process.

The deterioration in staff satisfaction observed in 2025, and in particular the emergence, for the first time, of a significant refusal rate to complete the questionnaire, can be interpreted as a signal of growing disengagement that goes beyond the issue of remuneration alone. The perception that work has become less stimulating and that career prospects are unclear may be linked to the increased administrative burden on medical staff, the reduction in available spaces, and the broader sense of organisational instability generated by repeated structural changes. These findings deserve careful consideration, as staff wellbeing is a well-established determinant of both quality of care and patient safety.[36]

Despite the challenges described above, the year 2025 saw the achievement of several important objectives. The activation of a Data Manager contract supported the management of clinical trial documentation and departmental data. Participation in national SIDeMaST campaigns on atopic dermatitis, skin cancer awareness, and vitiligo contributed to raising public and professional awareness of dermatological conditions. The Multidisciplinary Tumour Board meetings were held regularly every two weeks. This structured approach aligns with recent literature demonstrating that multidisciplinary team coordination is essential for managing complex cases and optimizing patient outcomes.[39] The unit joined the Regional Technical Group for Dermatology at the end of 2025, strengthening its integration within the regional healthcare network. The resolution of the histological report delivery non-conformity, through the introduction of separate appointments for suture removal and result communication, proved effective and was formally closed. Staff mandatory training requirements were met, including retraining courses as required by the 2025 corporate objectives. The number of scientific publications increased, including contributions to multicentre studies, with a parallel improvement in the impact factor of the journals in which

the unit published. Finally, the purchase of the new phototherapy unit, even if its installation is pending, represents a concrete step towards the resumption of a service that had been suspended since February 2025.

6. CONCLUSION

In conclusion what emerges clearly from this analysis is that quality certification is far from a bureaucratic exercise or a mere administrative burden. On the contrary, it represents one of the few structured mechanisms available to a healthcare organisation to make change visible, measurable, and sustainable over time. In a clinical environment where daily pressures, resource constraints, and the complexity of patient needs can easily obscure systemic inefficiencies, the discipline imposed by a quality management system, regular audits, non-conformity tracking, indicator monitoring, management reviews, creates the conditions for problems to be named, documented, and addressed rather than absorbed silently into routine practice.[40]

The tools employed in this process each contribute a distinct and complementary perspective. The SWOT analysis enables the organisation to situate itself strategically, acknowledging not only its internal vulnerabilities but also the external opportunities it can leverage and the threats it must mitigate. The Plan-Do-Check-Act cycle, with its iterative logic, provides the operational backbone of continuous improvement, ensuring that corrective actions are not isolated responses but part of a coherent and ongoing process of organisational learning.[40]

Taken together, these tools transform what might otherwise be perceived as abstract quality principles into concrete clinical and managerial practice. The management review itself, the document at the centre of this analysis, is perhaps the clearest expression of this: a structured annual exercise in which the organisation looks honestly at what it has achieved, what it has failed to achieve, and what it intends to do differently. This kind of institutional self-reflection is rare in healthcare, where the urgency of clinical demand often leaves little space for strategic thinking, and it is precisely the certification framework that creates the obligation, and the opportunity to engage in it.

It is also worth noting that the value of ISO 9001:2015 certification extends beyond the organisation itself. For patients, it offers a verifiable signal of commitment to quality and safety standards that goes beyond individual clinical excellence. For referring physicians and other healthcare providers, it supports confidence in the reliability of the unit's processes and the consistency of its outcomes. For institutional funders and regulators, it provides evidence of organisational maturity and accountability. And for the staff working within the unit, it offers (when implemented well) a shared language and a common framework for identifying problems and proposing solutions, contributing to a culture in which quality is understood as a collective responsibility rather than a top-down imposition.

This paper has shown that ISO 9001:2015 certification, far from being an end in itself, is a living process that reflects the daily reality of a complex clinical organisation in all its contradictions, its strengths and its vulnerabilities, its achievements and its unresolved challenges. It is precisely this capacity to hold complexity

without simplifying it that makes quality management a genuinely valuable tool for healthcare. The SCDU of Dermatology and Venereology of Novara represents a meaningful example of how a specialised clinical unit can use the structure of a quality management system not merely to comply with external requirements, but to build a more reflective, more accountable, and ultimately more effective organisation, one that is better equipped to deliver high standards of care to an increasingly complex and demanding patient population.

7. BIBLIOGRAPHY

1. Hussein, M., Pavlova, M., Ghalwash, M., and Groot, W. (2021). The impact of hospital accreditation on the quality of healthcare: a systematic literature review. BMC Health Serv. Res. *21*, 1057.
2. Ahmed, Z., Ellahham, S., Soomro, M., Shams, S., and Latif, K. (2024). Exploring the impact of compassion and leadership on patient safety and quality in healthcare systems: a narrative review. BMJ Open Qual. *13*, e002651.
3. Levink, I.J.M., Balduzzi, A., Marafini, I., Kani, H.T., Maeda, Y., and UEGJ Guideline Taskforce. (2024). Quality of clinical guidelines: It matters as it impacts patient care. United European Gastroenterol. J. *12*, 664–666.
4. Lewis, K., and Hinchcliff, R. (2023). Hospital accreditation: an umbrella review. Int. J. Qual. Health Care *35*, mzad007.
5. Miziara, I.D., and Miziara, C.S.M.G. (2022). Medical errors, medical negligence and defensive medicine: A narrative review. Clinics (Sao Paulo) *77*, 100053.
6. Oyebode, F. (2013). Clinical errors and medical negligence. Med. Princ. Pract. *22*, 323–333
7. Institute of Medicine (US) Committee on Quality of Health Care in America. (2000). To Err is Human: Building a Safer Health System. L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds. (National Academies Press (US)).
8. Mattiuzzi, C., Plebani, M., and Lippi, G. (2024). Recent mortality rates due to complications of medical and surgical care in the US. Diagnosis (Berl) *11*, 443–445.
9. Reason, J. (2000). Human error: models and management. BMJ *320*, 768–770.
10. Althobaiti, F.M. (2026). The effects of leadership on patient safety culture in health care: a systematic review. BMC Nurs. *25*, 125.
11. Wright, D.S., Kleppe, M., Coleman, B.C., Funabashi, M., Ferguson, A.G., Brown, R., Rubinstein, S.M., Salsbury, S.A., and Pohlman, K.A. (2025). Patient safety culture research within the chiropractic profession: a scoping review. Chiropr. Man. Therap. *33*, 46.
12. Zhou, B., and Liu, L. (2026). A meta-analysis of factors influencing nurses' perceptions of patient care safety culture. Medicine (Baltimore) *105*, e46731.
13. Silva CF, Alvim ALS, Lemos RCPB, Carbogim FC, Santos TR, Siman AG, Dutra HS, and Ribeiro L (2025). Analysis of patient safety culture among professionals at a public teaching hospital. Rev Gaúcha Enferm. *46*, e20250105.

14. Autar KUD, van den Bos-Boon A, van Heesch GGM, van Dijk M, and Poley MJ (2025). Exploring patient safety culture and opportunities for improvement: a mixed-methods study in a Dutch paediatric intensive care unit. BMJ Open Qual. *14*, e003571.

15. Miziara, I.D., and Miziara, C.S.M.G. (2022). Medical errors, medical negligence and defensive medicine: A narrative review. Clinics (Sao Paulo) *77*, 100053.

16. Asmat, K., Dhamani, K., Gul, R., and Froelicher, E.S. (2022). The effectiveness of patient-centered care vs. usual care in type 2 diabetes self-management: A systematic review and meta-analysis. Front. Public Health *10*, 994766.

17. Hofman, D.E., Magrì, T., Moor, C.C., Richeldi, L., Wijsenbeek, M.S., and Waseda, Y. (2024). Patient-centered care in pulmonary fibrosis: access, anticipate, and act. Respir. Res. *25*, 395.

18. Goldfarb, M.J., Saylor, M.A., Bozkurt, B., Code, J., Di Palo, K.E., Durante, A., Flanary, K., Masterson Creber, R., Ogunniyi, M.O., Rodriguez, F., et al. (2024). Patient-centered adult cardiovascular care: a scientific statement from the American Heart Association. Circulation *149*, e1176–e1188.

19. Tal, O., Barnea, R., and Tur-Sinai, A. (2023). Patient-centeredness-a cultural targeted survey among junior medical managers. Int. J. Equity Health *22*, 170.

20. Veronese F, Farinelli P, Zavattaro E, Zuccoli R, Bonvini D, Leigheb G, and Colombo E (2012). Basal cell carcinoma of the head region: therapeutical results of 350 lesions treated with Mohs micrographic surgery. J Eur Acad Dermatol Venereol. *26*, 838–843.

21. Veronese F, Boggio P, Tiberio R, Gattoni M, Fava P, Caliendo V, Colombo E, and Savoia P (2017). Wide local excision vs. Mohs Tübingen technique in the treatment of dermatofibrosarcoma protuberans: a two-centre retrospective study and literature review. J Eur Acad Dermatol Venereol. *31*, 2069–2076.

22. Fumai G, Morelli C, Menolascina F, Fontana A, and Laricchia G (2026). Evolution of Quality Management in Italian Healthcare (2016-2024) Beyond Mandatory Accreditation Through the International Organization for Standardization (ISO), Joint Commission International (JCI), and the New ISO 7101 Standard: A Scoping Review. Cureus. *18*, e107579.

23. World Medical Association (2024). WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. Helsinki: WMA.

24. Betlloch-Mas, I., Ramón-Sapena, R., Abellán-García, C., and Pascual-Ramírez, J.C. (2019). Implementation and Operation of an Integrated Quality Management System in Accordance With ISO 9001:2015 in a Dermatology Department. *Actas Dermosifiliogr. 110*(2), 92–101

25. Avruscio, G., Ragazzo, S., Ceccato, D., Adamo, A., Napoli, C., Cacco, L., Scalzotto, F., Canciani, M., Cognolato, M., Fedele, A., et al. (2022). Implementation of a quality management system according to ISO 9001:2015 standards in an Angiology Unit: an Italian experience. *Ann. Ig. 34*(6), 627–634

26. Ghrieb, Z., Walter-Petrich, A., Huang, J., Chevret, S., Montlahuc, C., Resche-Rigon, M., Kiladjian, J.J., Allaoua, S., and Abdeljalil, N. (2024). Chronologie de la certification ISO 9001:2015 et enquête de satisfaction au sein du centre d'investigations cliniques plurithématique (CIC-P) de l'historique hôpital Saint-Louis en période de pandémie du COVID-19. *Therapies 79*(4), 519–531

27. Pillot, T., Gahbiche, A., Duval, X., Bloch, V., and Jacob, A. (2025). Certification ISO 9001 : 2015 de l'unité des essais cliniques d'un centre hospitalier universitaire. *Therapies*, S0040-5957(25)00080-0. Advance online publication.

28. Moyce, S., Claudio, D., and Velazquez, M. (2023). Using the PDCA cycle to uncover sources of mental health disparities for Hispanics. *Int. J. Ment. Health Nurs. 32*(2), 556–566

29. Pan, L. (2026). Enhancing Medical Record Quality in Psychiatric Care Through PDCA Cycle Management. *Risk Manag. Healthcare Policy 19*, 603196

30. Cui, X., Liang, C., Jia, S., Bi, Y., Li, Q., Zhao, X., Wang, M., Tang, Z., Ou, T., Dai, X., et al. (2026). Effect of PDCA cycle on critical value management in primary healthcare institutions: an interrupted time series study. *Front. Health Serv. 6*, 1745945 .

31. P, R.R., Shafiq, N., K, N., Kumari, D., Dhillon, M.S., Arora, P., Chouhan, D.K., Saini, U.S., Dadra, A., Angrup, A., et al. (2026). Plan-do-check-act (PDCA) cycle analysis for antimicrobial stewardship of orthopedic patients in trauma center-implementation research. *Antimicrob. Steward. Healthcare Epidemiol. 6*(1), e126 .

32. Azienda Ospedaliero Universitaria "Maggiore della Carità" di Novara (2025). Standard di Servizio – SCDU Dermatologia e Venereologia. Available at: https://www.maggioreosp.novara.it/download/sts-dermatologia-29-aprile-2025/ (accessed June 26, 2026).

33. International Organization for Standardization (2015). ISO 9001:2015 – Quality Management Systems: Requirements. Geneva: ISO.

34. Zhou, L., Zhong, Y., Han, L., Xie, Y., and Wan, M. (2025). Global, regional, and national trends in the burden of melanoma and non-melanoma skin cancer: insights from the global burden of disease study 1990–2021. Sci. Rep. *15*, 5996.

35. Sendín-Martín, M., Bueno-Molina, R.C., Hernández-Rodríguez, J.-C., Cayuela, L., Cayuela, A., and Pereyra-Rodríguez, J.-J. (2026). Incidence and mortality of nonmelanoma skin cancer in Europe: current trends and challenges. Clin. Transl. Oncol. *28*, 302–319.

36. Aiken, L.H., Lasater, K.B., Sloane, D.M., Pogue, C.A., Fitzpatrick Rosenbaum, K.E., Muir, K.J., McHugh, M.D., and US Clinician Wellbeing Study Consortium (2023). Physician and nurse well-being and preferred interventions to address burnout in hospital practice: factors associated with turnover, outcomes, and patient safety. JAMA Health Forum *4*, e231809.

37. Nast, A., Altenburg, A., Augustin, M., Radtke, M., Rustenbach, S.J., and Werner, R.N. (2021). EuroGuiDerm Guideline on the systemic treatment of Psoriasis vulgaris - Part 2: specific clinical situations and management. J. Eur. Acad. Dermatol. Venereol. 35, 281–317.

38. Williams, H.C., Schmitt, J., Thomas, K.S., Spuls, P.I., Simpson, E.L., Apfelbacher, C.J., Chalmers, J.R., Furue, M., Katoh, N., Gerbens, L.A.A., et al. (2022). The HOME Core outcome set for clinical trials of atopic dermatitis. J. Allergy Clin. Immunol. 149, 1899–1911.

39. Hafeez, Z., Johnson, A., Nester, N., Mani, H., Blackham, A., McIntosh, A., Davis, L., Miller, A., Bauman, A., Horton, M., et al. (2025). Impact of adopting a multidisciplinary care delivery model on treatment effectiveness and outcomes in stage III melanoma patients at a community-based academic institution: a retrospective study. Cureus 17, e79703.

40. Boukhaldi, J., Kechkar, H., Errami, A., Benhsaien, I., Kamal, N., Bousfiha, A.A., and El Bakkouri, J. (2026). ISO 9001 in hospitals: a systematic review and implementation framework for clinical services in emerging countries. Int. J. Qual. Health Care 38, mzag006.