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PROTOCOL

Organizational outcomes of the Caring Nurse in the Emergency Department in a major metropolitan hospital: a retrospective study protocol

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Findings:

A systematic literature review was conducted to analyze and synthesize the role and competencies of the clinical research nurse in onco-hematology at the international level, identifying six main functions and seven competency areas, while highlighting ongoing ambiguities in professional scope.

ABSTRACT

BACKGROUND: Waiting in the Emergency Department (ED) is a critical moment for user experience and the relationship with the healthcare system. Overcrowding, aggression, and early departures are well-known issues that have significant clinical, organisational, and economic impacts. Literature suggests that communication- and relationship-centred interventions can improve user experience and reduce aggressive behaviour.
OBJECTIVES: This study aims to evaluate the impact of introducing the Caring Nurse (CN) role in ASST Niguarda's Emergency Department (ED). Primary objectives are: 1) to quantify aggressive incidents toward healthcare staff; 2) to quantify the number of patients leaving without being seen. Secondary objectives include measuring satisfaction among users, caregivers, and healthcare professionals.
METHODS: A retrospective, descriptive, single-centre study will be conducted using data collected from May 2023 to May 2025. Data will be drawn from hospital records and ad hoc questionnaires, which will undergo validation and verification. Statistical analysis includes normality testing, exploratory factor analysis, and reliability assessment (Cronbach's alpha).
EXPECTED RESULTS: It is hypothesised that the CN will lead to a reduction in aggression and early departures, as well as an increase in perceived satisfaction. The findings will contribute to the national literature on the effectiveness of CN and may support the adoption of innovative care models.
CONCLUSIONS: This study will help evaluate the impact of a relational and communication-focused intervention in a high-complexity emergency care setting.

KEYWORDS: *Research Nurse, Clinical Trial Nurse, Study Nurse, Role, Cancer, Neoplasm, Trial*

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PROTOCOLLO

Esiti organizzativi del Caring Nurse nel Dipartimento di Emergenza di un grande ospedale metropolitano: protocollo di uno studio retrospettivo

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Riscontri:

È stata condotta una revisione sistematica della letteratura per analizzare e sintetizzare ruolo e competenze dell'infermiere di ricerca clinica in oncoematologia a livello internazionale, evidenziando sei principali funzioni e sette aree di competenza, ma anche persistenti ambiguità rispetto all'ambito professionale.

ABSTRACT

PREMESSA: L'attesa nel Dipartimento di Emergenza (ED) è un momento critico per l'esperienza dell'utente e per il rapporto con il sistema sanitario. Il sovraffollamento, le aggressioni e le partenze anticipate sono problemi ben noti che hanno un impatto clinico, organizzativo ed economico significativo. La letteratura suggerisce che gli interventi incentrati sulla comunicazione e sulla relazione possono migliorare l'esperienza dell'utente e ridurre i comportamenti aggressivi.
OBIETTIVI: Questo studio si propone di valutare l'impatto dell'introduzione del ruolo dell'Infermiere di Cura (CN) nel Dipartimento di Emergenza (ED) dell'ASST Niguarda. Gli obiettivi primari sono: 1) quantificare gli episodi di aggressività nei confronti del personale sanitario; 2) quantificare il numero di pazienti che si allontanano senza essere visitati. Gli obiettivi secondari comprendono la misurazione della soddisfazione di utenti, operatori e personale sanitario.
METODI: Verrà condotto uno studio retrospettivo, descrittivo, monocentrico, utilizzando i dati raccolti dal maggio 2023 al maggio 2025. I dati saranno ricavati dalle cartelle cliniche e da questionari ad hoc, che saranno sottoposti a convalida e verifica. L'analisi statistica comprende test di normalità, analisi fattoriale esplorativa e valutazione dell'affidabilità (alfa di Cronbach).
RISULTATI ATTESI: Si ipotizza che il CN porti a una riduzione dell'aggressività e delle partenze anticipate, nonché a un aumento della soddisfazione percepita. I risultati contribuiranno alla letteratura nazionale sull'efficacia della CN e potranno sostenere l'adozione di modelli assistenziali innovativi.
CONCLUSIONI: Questo studio contribuirà a valutare l'impatto di un intervento relazionale e comunicativo in un contesto di emergenza ad alta complessità.

KEYWORDS: *Infermiere Di Ricerca, Clinical Trial Nurse, Study Nurse, Ruolo, Cancro, Neoplasia, Trial*

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BACKGROUND

Waiting in the Emergency Room represents a critical moment in the relationship between citizens and the National Health Service. In our country, the issue of overcrowding in emergency services has been known for some time, to the point that the Ministry of Health has issued national guidelines for its management (1). Overcrowding translates into increased time spent waiting for health services, which can lead to dissatisfaction, distrust of the institution, reduced expected clinical care outcomes, and increased aggressiveness. Two systematic reviews suggest that the patient's experience in the Emergency Department while waiting influences their clinical risk levels (2), health outcomes and behaviour within the service (3). Regarding aggression, a recent meta-analysis (4) reports a prevalence of aggressive actions (verbal and physical) by patients against nurses of 28%, with a 95% CI [19-38]. The studies included in the analysis originate from different continents; however, the Italian data analysed by the authors align with the overall estimates. Finally, users' experience while waiting in the emergency room is a known determinant of the number of "left without being seen", i.e. subjects who leave the service after triage without seeing the doctor, as underlined by a recent overview of reviews (5). This phenomenon has organisational and economic repercussions for the hospital.

In parallel with the studies that have investigated the components of the problem, numerous works have analysed possible solutions moving on two main strands: on the one hand, the organisational one, mainly through interventions aimed at reducing overcrowding, such as bed management (6), on the other hand, the relational one and the taking charge by trained and dedicated figures. The literature highlights the benefits of patient-centred care in enhancing the emergency room experience for users, who perceive high levels of attention to their situation from staff and feel more involved in decision-making (7). At the same time, adopting an approach based on effective communication strategies helps raise user satisfaction levels (8), which is a key indicator for healthcare organisations and is associated with a reduction in the risk of aggressive actions, as indicated by a recent systematic review (9). Ineffective communication is often associated with anger, frustration, stress and fear, even on the part of the companions. For the latter, the experience of waiting takes on an emotional value linked to concern for the health of the loved one: the prolongation of the wait outside work areas to which they cannot access adds to this feeling, contributing to determining the perception of quality of service and behaviour in the emergency room (9). In addition to the effects on users, the literature (McIntyre, Crilly & Elder, 2024) highlights the positive impact of effective communication on the work environment as a protective factor against burnout and the intention to leave the profession.

Numerous studies have analysed the characteristics and outcomes of an effective relationship between nursing staff and users, referring to the latter as accompanying persons. A recent scoping review (10) suggested the usefulness of a nursing figure dedicated not to managing patient flow but to communication with users, explaining waiting times and health procedures proposed to patients, facilitating the exchange of information between users and the health team, and providing support. The same authors have emphasised the possibility of using the waiting period to provide health education that is useful to users in managing their health condition. Other authors have worked on the figure of the emergency waiting room nurse, also known as the "caring nurse", which is a nursing figure with specific training and professional experience dedicated to the activities described above (11,12).

In Italy, the literature is scarce due to the recent introduction of the concept of caring nursing and the limited number of hospitals that have implemented it, as well as the lack of documentation. The ASST Grande Ospedale Metropolitano Niguarda was the first healthcare organisation to include this figure in the Emergency Department. In May 2023, the Directorate of Healthcare and Social Professions identified four caring nurses (CNs) based on their professional curriculum. A public examination was conducted to identify the coordinator of the caring nurses' group. The exam was based on the curriculum

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vitae of the candidates, who were all nurses from the emergency department of the hospital; according to the literature (10-12), experience in the emergency room and knowledge of organisational aspects such as patient flow, protected discharge protocols, and patient admission criteria to the Intensive Care Unit were the criteria used to choose the coordinator. The Directorate provided formal and economic acknowledgement of the new role to this person; three more caring nurses were identified based on their CVs, with formal acknowledgement of the role but no additional salary. A meeting was held with the Directorate, the head nurse of the Emergency Department and the four caring nurses to share goals and areas of intervention. Finally, the organisation's communication office was involved in giving visibility to the caring nurses on institutional social media accounts, websites, and posters placed at the main entrance of the hospital and in the emergency department.

The potential usefulness of the CN in the healthcare context was supported by the complexity of the geographic area in which the hospital is located: Niguarda is a reference point in the Milan metropolitan area for various emergency and urgent situations. It has numerous wards capable of managing patients in complex situations (major traumas, major burns, major spinal cord injuries, damage control surgery), an operating theatre with 75 rooms, land emergency vehicles, and helicopters. The Emergency Department welcomes an average of 300 adults daily. In this context, the NCs guide users, providing indications and information on triage, expected waiting times, and healthcare pathways; they accompany patients and caregivers throughout the entire Emergency Department stay, from triage to discharge or hospitalisation. The patients entrusted to them are those admitted to the short-intensive observation area and the admission room, an area where patients who require hospital admission wait to be escorted to their designated hospital units.

Based on the characteristics of the Emergency Room service and the results obtained by the authors of the existing studies on the caring nurse, the hypothesis behind the implementation of the CN at Niguarda was an improvement in the satisfaction of users and healthcare personnel, as well as a reduction in aggressive acts and the number of "left without being seen". To assess satisfaction levels, two questionnaires have been prepared by the hospital's nursing management, dedicated to users and healthcare professionals of the Emergency Room. Two years after the project's initiation, the hypothesis described above can be verified in a large catchment area and among staff through the analysis of data collected to date, also contributing to the national literature on the subject.

AIMS

The goals of this study are:

- Primary goal 1: to quantify the aggressive events by users towards health care workers compared to the period before the implementation of the caring nurse.
- Primary goal 2: To quantify the number of patients leaving without having been seen compared to the period before the implementation of the caring nurse.
- Secondary goal 1: to measure the satisfaction of the patient and their companions when leaving the Emergency Department (discharge home, discharge to the territory, hospitalisation) regarding the experience with the caring nurse and with the Operating Unit.
- Secondary goal 2: to measure the satisfaction of the Emergency Department healthcare staff concerning the impact of the caring nurse on the work environment.

METHODS

Study design

A descriptive, retrospective, single-centre design will be employed to analyse data from May 2023 (introduction of the caring nurse at ASST Niguarda) to May 2025.

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Sample

All patients and caregivers will be enrolled during discharge or admission from the ED from May 2023 to May 2025. The inclusion criteria are those established since the introduction of the caring nurse for the administration of the satisfaction questionnaire required by company procedures: age ≥ 18 years, ability to understand the Italian language, absence of space/time/person disorientation according to the assessments carried out during the stay in the emergency room based on the clinical protocols of the department, informed consent to the compilation of the satisfaction form provided by the Company for the caring nurse. All caregivers who have expressed informed consent and filled out the form will also be enrolled. All nurses and doctors working in the Emergency Department as employees of ASST Niguarda from May 2023 to May 2025, who, subject to informed consent, have completed the company satisfaction questionnaire concerning the working environment, will also be enrolled.

Sample size

The literature criteria will be followed, calculating a minimum of 100 participants for exploratory factor analysis (13) with a responders-to-items ratio of 6:1 (MacCallum et al., 1999). Based on these considerations and the annual number and characteristics of the patients managed by the caring nurse, a sample size of 200 subjects is estimated.

Data collection instruments

Data related to Primary Objectives 1 and 2 will be extracted from the hospital records managed by the Niguarda quality office. Regarding the secondary objectives, the questionnaires administered to patients discharged or hospitalised from the Emergency Department (Annexe 1) and those administered to nursing and medical staff operating in the Emergency Department from May 2023 to May 2025 will be analysed. The two tools were created ad hoc, as no validated questionnaires were found in the literature. To ensure the quality of the measure, they will undergo validity and reliability assessment.

Data analysis plan

Continuous variables will be described as the mean and standard deviation if normally distributed (based on the results of Shapiro-Wilk's test) or as the median and interquartile range (IQR). Categorical variables will described by frequencies. The reliability of the user satisfaction questionnaires will be evaluated by calculating Cronbach's alpha, excluding each of the five items related to satisfaction with the caring nurse. Regarding the questionnaires completed by patients and their caregivers, construct validity will be assessed using exploratory factor analysis. The factors will be extracted using principal axis factorisation and rotated with the Oblimin method based on scientific literature (14). The number of factors was determined using parallel analysis (15), and the loadings were evaluated according to the Stevens criterion (Stevens, 2009). Bartlett's sphericity test and Kaiser-Meyer-Olkin'2 (KMO) measure of sample adequacy were used to assess the suitability of the sample for analysis (Ismail, 2008). Communality ≥0.40 was deemed acceptable (14). The significance threshold for all analyses was set at a p-value of 0.05. The analysis will be performed using STATA® 18 for MacOS (STATACorp, Inc., USA).

Ethical aspects

The study will be conducted in compliance with the current Italian legislation on data processing and the Helsinki Declaration (13). At the time of data collection, subjects were informed of the business and scientific purposes of the study, and they were given the freedom to refuse participation or withdraw from the study at any time without providing reasons. Failure to participate and/or withdraw from the practice of patients does not affect in any way or at any time the diagnostic-therapeutic-assistance path of the subjects (in the case of users) or the working relationship with the Company (in the case of professionals). All the data collected in the present

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study will be analysed in an aggregate and anonymous form. The questionnaires did not immediately provide for the attribution of an identification code or the indication of personal data that could be used to identify the subjects. According to the policy of the Company Management of the Health and Social Health Professions, data regarding aggressions and those left without being seen have always been collected as simple counts without any identifying data of the subjects.

DISCUSSION

The introduction of the Caring Nurse (CN) in the Emergency Department of ASST Niguarda represents an organisational and relational innovation aimed at enhancing both patient and healthcare staff experiences in a high-complexity setting. The expected outcomes, consistent with international literature, include a reduction in aggressive incidents toward healthcare workers, a decrease in the number of patients leaving without being seen, and an increase in perceived satisfaction among patients, caregivers, and staff.

This protocol describes a retrospective analysis of data collected over two years following the CN's implementation

nursing modlsly enhancsThe implementation of the CN takes place in a metropolitan context of high complexity, where effective communication and relational care can add significant value to perceived service quality and organizational well-being.

CONCLUSIONS

Although results are not yet available, this study protocol aims to provide evidence of the effectiveness of the Caring Nurse in improving organisational and relational outcomes in the Emergency Department. The expected findings may contribute to the national literature and support strategic decisions in healthcare, promoting person-centred and communication-focused care models.

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