NURSING

Integration of the fundamental of care framework into the clinic (the CONFORM study): A quasi-experimental pre-post implementation study protocol

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Keywords

Patient-centred care • Nursing interventions • Quality improvement • health outcomes • Evidence-based nursing

Summary

Introduction. *Fundamental care addresses the essential physical and psychosocial needs of patients and is critical for safe, high-quality nursing practice. Despite growing awareness of its value, it remains one of the most neglected areas in clinical care. The Fundamentals of Care (FoC) Framework provides a structured approach to support its delivery, yet its practical implementation remains limited and underexplored. This study aims to evaluate the effectiveness of integrating the FoC Framework into nursing practice to reduce patient length of stay in medical and surgical wards.*

Methods. *A quasi-experimental pre-post implementation study will be conducted over 15 months in one medical and two surgical wards. The FoC Framework will guide interventions targeting key needs (nutrition, elimination, mobility, and education) identified through focus groups with nurses, patients, and caregivers. Following framework introduction, a six-month phase of individualised care will be implemented. Data on interventions and outcomes will be collected daily via the Electronic Health Record, both before and after implementation. The primary outcome is length of stay; secondary outcomes include adverse events, readmissions, patient and nurse satisfaction, turnover intentions, complaints, discharge rates, needs assessments, frequency of interventions, and goal achievement. Analyses will use t-tests or Mann-Whitney tests. Multivariable regression models will be considered for adjusting for confounding factors.*

Conclusion. *This is the first protocol that will assess the implementation of the FoC Framework in clinical practice. Findings will contribute robust evidence on its potential to improve care quality, meet essential patient needs, enhance satisfaction among patients and staff, and reduce adverse outcomes.*

Introduction

The concept of fundamental care has evolved over time, developing alongside the conceptual interpretations of nursing care, bringing attention back to fundamental care and its importance and relevance to nursing practice [1]. As early as 2013, an investigation known as the Francis Report, initiated in the United Kingdom following a series of patient safety incidents, identified poor leadership and care quality, particularly regarding essential aspects such as nutrition and elimination, highlighting the need for a radical transformation of healthcare systems [2]. More recently, the International Learning Collaborative [3] defined fundamental care as "nursing actions that respect and focus on a person's fundamental needs" and developed the Fundamental of Care (FoC) Framework as a conceptual reference [4, 5]. The FoC framework outlines all aspects involved in delivering safe, effective, and high-quality fundamental care. In this context, a previous study identified the fundamental care needs, such as nutrition, elimination, personal hygiene, mobility, and dignity [6], emphasizing that basic nursing care is highly valued and recognized by patients as necessary and important. The FoC framework underlined the necessity of integrating these various fundamental needs, encompassing physical needs (*e.g.,* nutrition, mobility, elimination) and psychosocial needs (*e.g.,* respect for choices, communication, education, and information) [7], and the importance of establishing a positive and trusting relationship with both the patient and their families/caregivers to meet these needs [8].

Subsequently, basic nursing care has also been recognized by other studies as a fundamental element of care [9] and an increasing number of studies reference the FoC Framework.

An analysis conducted in 2018, involving both nurses and patients, identified three types of factors that can influence the delivery of FoC needs: individual factors of the nurse or patient, organizational factors, and interpersonal factors. This study highlighted how these three aspects must be addressed globally because both nurses and patients share a common perspective, which influences the delivery of FoC [10]. However, FoC is recognised as one of the areas of nursing care more frequently neglected [11], resulting in missed care. Several studies highlighted the global prevalence of missed care [12-14] and reported the negative outcomes related to them. Failure to ensure adequate

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quality of nursing care leads not only to discomfort and dissatisfaction but also to broader patient safety deficiencies [15].

Neglecting FoC leads to harmful and very concerning consequences, including health complications, loss of functional autonomy, damage to dignity and self-esteem, decreased quality of life and well-being, compromised safety, and even death. Therefore, it is essential to focus on the person "as a whole", to prevent nursing care from becoming merely a set of technical activities that do not address the patient's real needs [14]. While the potentially harmful consequences of inadequate nursing care and the importance of optimizing it have been particularly highlighted for the elderly population [2, 16], it is imperative to emphasize that basic care is essential for every human being and significantly impacts quality of life, well-being, and health outcomes [17]. Kitson et al.'s (2022) study has further propelled this perspective, providing a new view that recognizes a person's fundamental care needs throughout their life span, through the initial description of what is termed the Caring Life-course Theory [18].

For all these reasons, it is crucial that not only healthcare professionals but also society at large become increasingly aware of the fundamental care needs and appreciate their optimal delivery [17]. Indeed, the current challenge is to ensure that the FoC are provided optimally [10] and a recent position statement from the International Learning Collaborative highlighted the importance of an ongoing action from healthcare leaders to prioritize FoC in clinical practice [19]. Despite greater awareness of the importance of FoC in the last decade, the existing literature still considerably lacks robust evidence on the implementation the FoC framework in clinical practice. It is necessary to develop a foundational scientific base that will enable the future development of evidence-based guidelines for healthcare professionals to deliver FoC to patients [20].

Methods

Aims

The primary aim of this study is to obtain evidence on the effectiveness of implementing the "Fundamentals of Care" – FoC framework into nursing clinical practice in terms of reduction of length of patients' stay in the Medical and Surgical wards.

The secondary aim of this study is to assess the effectiveness of the implementation of the FoC framework on a series of patients', organizational and nurses' outcomes. For patient outcomes this study will assess: 1) adverse nursing-sensitive outcomes (falls, catheter-associated urinary and bloodstream infections, pressure injuries, restraints, readmissions); 2) patient needs (elimination, nutrition, mobilization, therapeutic education, intra-team communication); and 3) patients' or their family's satisfaction. For nurse outcomes this study will assess: 1) nurse satisfaction; 2) positive impact on nurse engagement; and 3) reduction in the intention to leave. For organizational outcomes this study will assess: 1) the impact on the rate of home discharges and 2) the number of readmissions to the wads participating in this study.

Design

A quasi-experimental pre-post implementation study design will be adopted for this study. Data will be collected from the Electronic Health Records (Hospital Discharge Database), the integrated electronic medical records (EMR), and two surveys. The STROBE checklist for observational studies will be followed for the reporting of this study [21].

Study setting and sample

This study will be conducted in medical and surgical wards of the Ordine Mauriziano Hospital in Turin (Italy). The Mauriziano hospital has a substantial bed capacity, accommodating a wide range of inpatient services across various medical and surgical specialties. In this study, one medical and two surgical wards will participate.

Inclusion and/or Exclusion Criteria

Patients who meet the inclusion criteria will be recruited to this study. Inclusion criteria for patients are: 1) being adult (>18 years old); 2) being admitted to one of the medical or surgical departments participating in this study; 3) being admitted and discharged during the study period (6-months pre intervention or 6-months after intervention). For nurses, the inclusion criterion is working in the study wards during the 6-month pre-intervention or during the 6-month post-intervention phase. Exclusion criteria are patients under 18 years of age and nurses that did not work in the study wards during the entire pre-intervention or post-intervention period.

Intervention

The FOC framework [3] has been applied to some areas of person's fundamental needs, identified through focus group methodology by nurses, patients, and caregivers from the wards involved in the quasi-experimental implementation study. It has been implemented over a period of 15 months in three wards: one medical and two surgical. The intervention included the following activities:

- an average of 130 hours of training (on FOC framework, organisational models, assessment tools and data collection procedures) for the entire technical group and nursing staff in the wards participating in the study;
- modification of nursing documentation tools for care planning and handover, introducing SBAR (Situation, Background, Assessment, Recommendation) tool;
- change in skill mix staffing: increase in nursing staff from a ratio of 1 nurse per 9.5 patients in the medical area and 1 nurse per 7 patients in the surgical area to an average ratio of 1 nurse per 6 patients in both medical and surgical areas and the reduction of the

percentage of nurse assistants to 40% of the nursing staff per each ward;
- improved shared spaces such as indoor and outdoor common areas for patients;
- inclusion of volunteer association personnel presence for approximately 4-6 hours per day;
- increase in care equipment (wheelchairs, screens, bedside cabinets);
- extension of visiting hours for families from 4 hours to 8 hours per day.

Study procedures

Patients admitted to the study wards will be cared for according to the FOC framework [3] during the 6-months post implementation period. Each patient's basic needs will be assessed, a dedicated care plan will be created and implementation of targeted interventions for unmet needs will be performed. Daily interventions and outcomes will be evaluated to ensure that the patient's needs are met. The areas of need being studied include nutrition, elimination, mobility, and therapeutic education. These areas have been chosen considering the results of the focus groups performed with the nurses of the included wards. All data regarding nursing interventions and outcomes will be collected through the Electronic Health Record before and after the FoC implementation.

Primary outcome

The primary outcome will be reduction of length of stay from pre- to post-intervention. Length of stay will be extracted through the Electronic Health Records (Hospital Discharge Database).

Secondary outcomes

Several secondary outcomes will be considered. Firstly, all secondary outcomes will be analysed in terms of absolute number for a direct comparison of each outcome between the pre- to post-intervention and in terms of key performance indicators (KPIs) to measure the global impact of the intervention from patient and nurse and organizational perspective.

Number of adverse events will be determined by counting the number of falls, catheter-associated urinary and bloodstream infections, pressure ulcers and restraints. These outcomes were chosen as they are considered important nursing outcomes in surgical and medical departments [22, 23]. Number of readmissions will be calculated for patients discharged and re-hospitalized in the same or different ward during the study period.

Patient's satisfaction, nurse's satisfaction and impact on nurse engagement and intention to leave will be assessed with specific surveys. The patient's satisfaction will be assessed through the CAHPS Hospital Survey [24]. This survey will be filled by the patient at discharge from the included ward. The nurse's satisfaction will be assessed through will be assessed through a single item, which asked nurses, "How satisfied are you with your current job?". Nurses could respond using a Likert scale ranging from "very satisfied" to "very unsatisfied" [25]. The impact on nurse engagement will be assessed through the Utrecht Work Engagement Scale [26]. This is a 3-item instrument (measuring the dimensions of vigour, dedication, and absorption) with response scale from 0 ("Not at all") to 6 ("Very much"). The total score can be calculated by averaging the responses of the items. Higher scores indicate greater work engagement. Intention to leave will be assessed by a single question asking respondents whether they intend to leave their current hospital within one year (possible answers will be yes/no) [25]. This survey will be filled by the nurse at a single time point during the data collection. All surveys where previously validated and used for other studies conducted by the research team [27, 28].

The number of reports and complaints will be assessed during the study period. All reports/complaints will be considered only if they will be referred to patients admitted during the study period. Reports/complaints will be considered if received at maximum two months after the end of the study period. Home discharges will be assessed as the number of discharges at home with / without home care. In this study, discharges at home will be interpreted positively, as the patient discharged at home will represent a lower occurrence of complications or complexity, compared to patients discharged to other facilities, other departments or who died.

Patients' needs will be assessed in terms of elimination, nutrition, mobility and therapeutic education. For each dimension, a mean of the assessments per day will be reported. For each patient's need, it will be collected the number of assessments per day, the number of interventions performed for resolving patient's care need per hospital stay and the number of patients achieving the care goal after receiving the intervention.

For each of these secondary outcomes, the related KPI will be calculated. The KPI will consider as denominator the total number of patients assessed or that received the intervention during the study period (Tabs. I, II).

Strategies to Minimize the risk of potential biases

To minimize the risk of selection bias, the inclusion and exclusion criteria specified in the protocol will be strictly adhered to. Reporting bias will be minimized by presenting all results obtained for primary and secondary outcomes, at least in the form of tables and/or figures. To reduce the risk of detection bias, blinding or masking of outcome assessors will be implemented. Thus, the statistician conducting the analyses will work on a blinded database (without indications regarding group membership) and will not be aware of the participants' group membership during the analyses.

Recruitment Procedure

A cohort will be identified through simple random sampling of EMRs from all patient discharges during the observation periods. A total of 450 records will be selected for each period (pre and post implementation) to determine the difference in the average length of stay between the two phases. The sample size calculation was based on the Wilcoxon–Mann–Whitney test, with

Tab. I. Description of outcome key performance indicator and related calculation method.

Outcome indicator	Description
Adverse events*+	Number of adverse events (falls, catheter-associated urinary and bloodstream infections, pressure injuries, restraints) / Total number of patients in the reference period
Readmissions*	Number of readmissions to the included ward / Total number of patients admitted during the reference period in the same ward
Patient satisfaction#	Number of satisfied patients / total number of patients in the reference period
Nurse satisfaction#	Number of satisfied nurses / total number of nurses
Impact on nurse engagement and intention to leave#	Number of nurses that demonstrate intention to leave / total number of nurses
Rate of home discharges*	Proportion of home discharges pre intervention / Proportion of home discharges post intervention
Reports and complaints§	Number of reports/complaints / total number of patients in the reference period

* Source: Electronic Health Records (Hospital Discharge Database), EMR. + Source: patient-reported incidents. # Source: BENE study survey. § Source: Public Relations Office.

Tab. II. Description of patient's needs key performance indicators and related calculation method.

Addressing of patients' needs	Documentation*	Interventions*	Achieved goals*
Elimination	Number of assessments documented by the team per day (if possible, identifying which member performed the assessment) / Total hospitalization days	Number of interventions prescribed by the team / Total number of patients requiring intervention prescription for the assessed need during the hospital stay	Number of patients achieving the goal after intervention by the team / Total number of patients receiving an intervention for the assessed need
Nutrition	Number of assessments documented by the team per day (if possible, identifying which member performed the assessment) / Theoretical total of assessments (3/day)	Number of interventions prescribed by the team (if possible, identify which member prescribed the intervention) / Total number of patients requiring intervention prescription for the assessed need during the hospital stay	Number of patients with the goal achieved after intervention by the team / Total number of patients receiving an intervention for the assessed need
Mobility	Number of assessments documented by the team (if possible, identifying which member performed the assessment) / Total hospitalization days	Number of interventions prescribed by the team (if possible, identify which member prescribed the intervention) / Total number of patients requiring intervention prescription for the assessed need during the hospital stay	Number of patients achieving the goal after intervention by the team / Total number of patients receiving an intervention for the assessed need
Therapeutic Education	Number of patients with documented assessments by the team (if possible, identifying which member performed the assessment) / Number of patients hospitalized in the reference period	Number of interventions prescribed by the team (if possible, identify which member prescribed the intervention) / Total number of patients requiring intervention prescription for the assessed need during the hospital stay	Number of patients achieving the goal after intervention by the team / Total number of patients receiving an intervention for the assessed need

* Suorce: EMR

80% power and a 5% level of significance. Based on these parameters, a total sample size of 900 patients (450 pre-intervention and 450 post-intervention) was deemed necessary to achieve adequate statistical power.

Data collection

Data regarding adverse events, readmissions, patient's needs and home discharges pre- and post-intervention will be collected from the integrated EMR and managed with a Case Report Form (CRF) prepared on the REDCap (Research Electronic Data Capture) platform hosted at the Ordine Mauriziano Hospital. REDCap is a secure, web-based application specifically designed to support data acquisition for research studies [29].

Only individuals officially registered as study investigators or those responsible for managing the REDCap application will receive authenticated access to the web platform and will upload/manage the data. Local investigators will be responsible for ensuring that the CRF is completed correctly and comprehensively.

Data will be retrospectively extracted through the facility's computerized system and anonymized by the facility to prevent the retrieval of sensitive patient data. The data collection form will be developed ad hoc and tested through an inter-rater reliability test. Local investigators involved in data collection from the EMR system will independently collect data from 10 complete patient records and compare the consistency of the

extracted data to ensure that the data collection form is a comprehensive and reliable tool.
Regarding patient satisfaction, nurse satisfaction, impact on nurse engagement, intention to leave and reports/complaints in the pre-intervention phase, data will be collected through a survey derived from other studies conducted by the research team [27, 28]. The wards of the Ordine Mauriziano Hospital involved in the current study participated in a national study on work well-being in 2022, the BENE study [27]. The BENE study required the participation of nurses and patients to a survey. The same variables will be assessed in the post-intervention phase, specifically data on nurse satisfaction, nurse engagement, and intention to leave the job, as well as patient satisfaction. In the post-intervention phase, data regarding nurses will be collected at a single time point during the 6-months of post intervention. The questionnaires are completely anonymous. Additionally, data on patient satisfaction will be collected by reviewing reports received by the Public Relations Office of the Ordine Mauriziano Hospital in Turin.

Data storage

All sensitive data collected will be stored in a server hosted by Ordine Mauriziano Hospital and will be accessible only by authorised investigators through the REDcap web platform. The extracted data will be available on local computer with limited access and protected by passwords and will be deleted at the end of the study.

Data analysis

The data collected will be analysed in an aggregated and anonymous form using descriptive and inferential statistics. The demographic characteristics of the sample and the levels recorded during the different assessments, before and after the intervention, will be described using descriptive indices such as mean and standard deviation or median with interquartile range (IQR). Additionally, the following statistical tests will be used (based on the type of data): 1) Student's t-test for independent samples or Wilcoxon-Mann-Whitney test to assess any differences between pre and post intervention for continuous variables; 2) Chi-square test (or non-parametric equivalent for non-normal distributions) to evaluate any differences between pre and post for categorical variables; 3) Student's t-test for paired data or Wilcoxon-Mann–Whitney test for intra-group evaluation of continuous variables. Multivariable regression models (*e.g.*, linear or logistic regression) will be considered to adjust for confounding factors (*e.g.,* patient's age and sex or ward) and to confirm the effect of the intervention on the outcomes.
Additionally, 95% confidence intervals of the mean lengths of stay stratified by medical or surgical departments will be provided. A significance level of 5% will be considered. To handle missingness of data, an analysis of the characteristics of the missing data will be carried out. Multiple imputation of these missing data will be implemented if appropriate [30]. Statistical analyses will be conducted with Jamovi V. 2.3.28 or similar software if necessary.

Ethical Considerations

This study will be conducted in full compliance with the international regulations [EU Directive 2001/20/EC], national regulation [Ministerial Decree 15 July 1997; Legislative Decree 211/2003; Legislative Decree 200/2007] regarding clinical trial and the principles of the Helsinki Declaration, to ensure the maximum protection of the participants. The study's promoter is committed to protecting sensitive personal data of the participants involved in the study as established by European regulations (EU GDPR 2016/679). All data will be treated to ensure participants' privacy according to current privacy regulations (EU GDPR 2016/679), and in any publications, data will be provided only in aggregated form. There are no compensations or reimbursements planned at any level. The principal investigator will have access to the system and will manage users and their credentials. Only specific users identified by the principal investigator will be able to access the data, and they will be assigned roles or permissions based on their needs. Each user will set a strong password (including uppercase and lowercase letters, numbers, and symbols).
This study has been approved by the Interhospital Territorial Ethics Committee "AOU Città della Salute e della Scienza di Torino." on 21st of May 2024 n°0067632. All deviations from the study protocol will be justified and reported to ensure transparency and integrity of the research.

Informed consent and data management

For the post-study, an informational leaflet and an informed consent form will be available in each included ward, explaining the study's structure, objectives, procedures, data collection, potential benefits of participation, and the absence of specific health risks, given that it involves an observational data collection. These details will be presented to interested individuals, who will have the freedom to sign informed consent and privacy statement for the processing of their data collected for the aims of this study.
An informational leaflet will be distributed to nurses, explaining the procedure and objectives of the study. Nursing staff will be asked to provide consent solely for completing the questionnaire and for the processing of data. These informational materials will be distributed to all nursing staff operating within the 3 facilities involved at the initiation of the study, and as new staff members are added throughout the study period.

Discussion

The FoC framework outlines all aspects involved in delivering safe, effective, and high-quality fundamental care [6]. Evidence continues to grow, showing that better hospital nurse staffing is associated with better

patient outcomes, including fewer hospital acquired infections, shorter length of stay, fewer readmissions, higher patient satisfaction, and lower nurse burnout [31]. The RN4CAST study recommended an average of six patients per nurse in hospital wards [32], and in this study the nursing staff will be adjusted following this recommendation to adequately implement the FoC framework.

The importance of this study lies above all in the intervention towards the satisfaction of the patient's needs (nutrition, mobilization, education and elimination), which previous literature has already shown to be linked to important outcomes with an impact on the healthcare system. Nutrition is an important subject of nursing care and one of the physical dimensions in the Fundamentals of Care framework. In addition, 82% of inpatients remain malnourished during their hospital stay and hospital malnutrition is associated with prolonged length of stay, increased hospital morbidity and mortality, high re-admission rates and low quality of life [33]. A systematic review [34] of randomized trials using early mobilization interventions showed decreased length of stay and improved functional status in older patients. Additionally, with early mobilization, 6 more patients every 100 were able to go home instead of nursing home or other care facility and hospital costs were reduced by $280 per patient per hospital stay. Therapeutic Patient Education has been found effective for improving numerous health and psychological outcomes in patients with chronic diseases [35]. On the other hand, to the best of our knowledge, to date no studies showed the association with adequate renal/bowel elimination management and patients' outcomes. Thus, this will be the first study to give insights on this topic. All these aspects will be assessed in this study, and the results will provide a concrete contribution to the scientific community regarding the improvements for patient outcomes by the Foc framework implementation in clinical practice.

Limitations

The first limitation of this study is that data collected through the EMR and uploaded on the CRF on REDcap web platform must be extracted by a local investigator with possible data entry errors. To minimize this limitation, a second local investigator will perform a cross-check on a random sample of data entered.

The second limitation of this study could be the amount of missing data. Even though the study is longitudinal some data measured on multiple time points could be missing.

A third limitation of this study lies in its quasi-experimental design, specifically the absence of a control group. This limits the internal validity of this study by reducing the ability to attribute outcome changes directly to the intervention and increasing the risk of selection bias. The presence of this bias will be assessed, and appropriate analysis will be performed to reduce this limitation.

Conclusion

This is the first protocol that will assess the outcomes of the implementation of the FoC framework. It will provide evidence on the effectiveness of the implementation of the FOC framework in the medical and surgical departments. The results provided by this study can be used as leverage for improving the response to the needs of the patient cared.

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Data availability statement

Not applicable.

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Ethics approval statement

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Conflict of interest statement

Nothing to declare.

Authors' contributions

All authors contributed to this manuscript. AB: Conceptualization, Methodology, Supervision, Writing-review & editing; GC: Investigation, Writing-original draft; SB: Investigation, Writing-review & editing; ADN: Investigation, Writing-review & editing; EG: Investigation, Writing-review & editing; OT: Investigation, Writing-review & editing; MS: Investigation, Writing-review & editing; AR: Investigation, Writing-review & editing; RS: Investigation, Writing-review & editing; GiC: Writing-original draft, Conceptualization, Methodology; LS: Conceptualization, Methodology, Supervision, Writing-review & editing.

References

[1] Lillekroken D. Teaching Basic Nursing Care: Nurse Preceptors' Perceptions about Changing the Teaching Context from the Clinical Setting to a School Simulation Lab. Int J Nurs Educ Scholarsh 2019;16(1). https://doi.org/10.1515/ijnes-2018-0033.

[2] UK Department of Health. Report of the Mid Staffordshire NHS Foundation. Trust public enquiry London, UK, 2013.

[3] Feo R, Conroy T, Jangland E, Muntlin Athlin Å, Brovall M, Parr J, Blomberg, K. Kitson, A.. Towards a standardised definition for fundamental care: A modified Delphi study. J Clin Nurs 2018;27:2285-99. https://doi.org/10.1111/jocn.14247. PubMed PMID: 29278437.

[4] Kitson AL, Dow C, Calabrese JD, Locock L, Muntlin Athlin Å. Stroke survivors' experiences of the fundamentals of care: a qualitative analysis. Int J Nurs Stud 2013;50:392-403. https://doi.org/10.1016/j.ijnurstu.2012.09.017.

[5] Kitson AL, Muntlin Athlin A. Development and preliminary testing of a framework to evaluate patients' experiences of the fundamentals of care: a secondary analysis of three stroke survivor narratives. Nurs Res Pract 2013;2013:572437. https://doi.org/10.1155/2013/572437.

[6] Kitson A, Conroy T, Wengstrom Y, Profetto-McGrath J, Robertson-Malt S. Defining the fundamentals of care. Int J Nurs Pract 2010;16:423-34. https://doi.org/10.1111/j.1440-172X.2010.01861.x.

[7] Kitson AL. The Fundamentals of Care Framework as a Point-of-Care Nursing Theory. Nurs Res 2018;67:99-107. https://doi.org/10.1097/nnr.0000000000000271.

[8] Feo R, Kitson A, Conroy T. How fundamental aspects of nursing care are defined in the literature: A scoping review. J Clin Nurs 2018;27:2189-29. https://doi.org/10.1111/jocn.14313.

[9] Zwakhalen SMG, Hamers JPH, Metzelthin SF, Ettema R, Heinen M, de Man-Van Ginkel JM, Vermeulen, H. Huisman-de Waal, G. Schuurmans, M.J. Basic nursing care: The most provided, the least evidence based - A discussion paper. J Clin Nurs. 2018;27:2496-505. https://doi.org/10.1111/jocn.14296.

[10] Conroy T. Factors influencing the delivery of the fundamentals of care: Perceptions of nurses, nursing leaders and healthcare consumers. J Clin Nurs 2018;27:2373-86. https://doi.org/10.1111/jocn.14183.

[11] Savoie C, Rey S, Yokota S, Dallaire C, Kimura S, Takatani S, Yano, Y. Fundamental Care's state of knowledge around the world: Where are we now? A scoping review. J Adv Nurs 2023;7:865-84. https://doi.org/10.1111/jan.15278.

[12] Cho E, Lee NJ, Kim EY, Kim S, Lee K, Park KO, Sung, Y.H. Nurse staffing level and overtime associated with patient safety, quality of care, and care left undone in hospitals: A cross-sectional study. Int J Nurs Stud 2016;60:263-71. https://doi.org/10.1016/j.ijnurstu.2016.05.009.

[13] Sasso L, Bagnasco A, Zanini M, Catania G, Aleo G, Santullo A, Spandonaro, F. Icardi, G. Watson, R. Sermeus, W. The general results of the RN4CAST survey in Italy. J Adv Nurs 2017;73:2028-30. https://doi.org/10.1111/jan.13066.

[14] Bagnasco A, Dasso N, Rossi S, Galanti C, Varone G, Catania G, Zanini, M., Aleo, G., Watson, R., Hayter, M., Sasso, L.. Unmet nursing care needs on medical and surgical wards: A scoping review of patients' perspectives. J Clin Nurs 2020;29:347-69. https://doi.org/10.1111/jocn.15089.

[15] Richards DA, Hilli A, Pentecost C, Goodwin VA, Frost J. Fundamental nursing care: A systematic review of the evidence on the effect of nursing care interventions for nutrition, elimination, mobility and hygiene. J Clin Nurs 2018;27:2179-88. https://doi.org/10.1111/jocn.14150.

[16] Garling P. Final report of the special commission of inquiry acute care services in NSW public hospitals Sydney, NSW: NSW Department of Premier and Cabinet; 2009. Available at: https://apo.org.au/node/4575 (Accessed on: 08/07/2025).

[17] Ottonello G, Napolitano F, Musio Maria E, Catania G, Zanini M, Aleo G, Timmins, F.; Sasso, L. Bagnasco, A.. Fundamental care: An evolutionary concept analysis. J Adv Nurs. 2023;79:2070-80. https://doi.org/10.1111/jan.15451.

[18] Kitson A, Feo R, Lawless M, Arciuli J, Clark R, Golley R, Lange, B. Ratcliffe, J. Robinson, S. Towards a unifying caring life-course theory for better self-care and caring solutions: a discussion paper. J Adv Nurs 2022;78:e6-20. https://doi.org/10.1111/jan.14887.

[19] Kitson A, Carr D, Feo R, Conroy T, Jeffs L. The ILC Maine statement: Time for the fundamental care [r]evolution. J Adv Nurs 2025;81:523-36. https://doi.org/https://doi.org/10.1111/jan.16108.

[20] Pentecost C, Frost J, Sugg HVR, Hilli A, Goodwin VA, Richards DA. Patients' and nurses' experiences of fundamental nursing care: a systematic review and qualitative synthesis. J Clin Nurs 2020;29:1858-82. https://doi.org/10.1111/jocn.15082.

[21] von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol 2008;61:344-9. https://doi.org/10.1016/j.jclinepi.2007.11.008.

[22] Murphy A, Griffiths P, Duffield C, Brady NM, Scott AP, Ball J, Drennan, J.. Estimating the economic cost of nurse sensitive adverse events amongst patients in medical and surgical settings. J Adv Nurs 2021;77:3379-88. https://doi.org/10.1111/jan.14860.

[23] D'Amour D, Dubois CA, Tchouaket E, Clarke S, Blais R. The occurrence of adverse events potentially attributable to nursing care in medical units: cross sectional record review. Int J Nurs Stud 2014;51:882-91. https://doi.org/10.1016/j.ijnurstu.2013.10.017.

[24] Centers for Medicare and Medicaid Services. Hospital Consumer Assessment of Healthcare Providers and Systems: Patients' perspectives of care survey. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS (Accessed on: 29/10/2024).

[25] McHugh MD, Kutney-Lee A, Cimiotti JP, Sloane DM, Aiken LH. Nurses' widespread job dissatisfaction, burnout, and frustration with health benefits signal problems for patient care. Health Aff (Millwood) 2011;30:202-10. https://doi.org/10.1377/hlthaff.2010.0100.

[26] Schaufeli WB, Shimazu A, Hakanen J, Salanova M, De Witte H. An ultra-short measure for work engagement: The UWES-3 validation across five countries. European Journal of Psychological Assessment 2019;35:577-91. https://doi.org/10.1027/1015-5759/a000430.

[27] Bagnasco A, Catania G, Zanini M, Musio ME, Mangiacavalli B, Aiken L, Sasso, L. Benessere professionale dell'infermiere e sicurezza delle cure in epoca pandemica. L'Infermiere. 2023;60:164-77. https://doi.org/10.57659/SSI.2023.014.

[28] Bagnasco A, Alvaro R, Lancia L, Manara DF, Rasero L, Rocco G, Burgio, A., Di Nitto, M., Zanini, M., Zega, M., Cicolini, G., Sasso, L., Mazzoleni, B. Working conditions, missed care and patient experience in home care nursing in Italy: An observational study. Public Health Nurs 2024;41:709-22. https://doi.org/10.1111/phn.13320.

[29] Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, McLeod L, Delacqua G, Delacqua F, Kirby J, Duda SN; REDCap Consortium. The REDCap consortium: Building an international community of software platform partners. J Biomed Inform 2019;95:103208. https://doi.org/https://doi.org/10.1016/j.jbi.2019.103208.

[30] Asendorpf JB, van de Schoot R, Denissen JJA, Hutteman R. Reducing bias due to systematic attrition in longitudinal studies: The benefits of multiple imputation. Int J Behav Dev 2014;38:453-60. https://doi.org/10.1177/0165025414542713.

[31] McHugh MD, Aiken LH, Sloane DM, Windsor C, Douglas C, Yates P. Effects of nurse-to-patient ratio legislation on nurse staffing and patient mortality, readmissions, and length of stay: a prospective study in a panel of hospitals. Lancet 2021;397:1905-13. https://doi.org/10.1016/s0140-6736(21)00768-6.

[32] Aiken LH, Sloane DM, Bruyneel L, Van den Heede K, Griffiths P, Busse R, Diomidous M, Kinnunen J, Kózka M, Lesaffre E, McHugh MD, Moreno-Casbas MT, Rafferty AM, Schwendi-

mann R, Scott PA, Tishelman C, van Achterberg T, Sermeus W; RN4CAST consortium. Nurse staffing and education and hospital mortality in nine European countries: a retrospective observational study. Lancet 2014;383:1824-30. https://doi.org/10.1016/s0140-6736(13)62631-8.

[33] Van Den Berg G, Vermeulen H, Conroy T, Van Noort H, De Van Der Schueren M, Huisman-de Waal G. Factors influencing the delivery of nutritional care by nurses for hospitalised medical patients with malnutrition; a qualitative study. J Clin Nurs 2023;32:5147-59. . https://doi.org/10.1111/jocn.16614.

[34] de Morton NA, Keating JL, Jeffs K. The effect of exercise on outcomes for older acute medical inpatients compared with control or alternative treatments: a systematic review of randomized controlled trials. Clin Rehabil 2007;21:3-16. https://doi.org/10.1177/0269215506071313.

[35] Loyal D, Ricci L, Villegente J, Ayav C, Kivits J, Rat AC. Healthcare providers perception of therapeutic patient education efficacy according to patient and healthcare provider characteristics. Chronic Illn 2023;19:233-49. https://doi.org/10.1177/17423953211058411.

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