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Evaluating the effects of polices on nursing care as promoted by the Veneto region: the research protocol and its implications for public health

A. Di Falco[1], C. Costa[2], M. Bottega[3], E. Fanton[2], A. Zambon[1], L. Brugnaro[1], S. Stevanin[2], E. Roncoroni[4], E. Allegrini[5], M. Degan[6], G. Capirossi[7], P. Bonesso[2], A. Palese[8], L. Saiani[9], D. Mantoan[2]

Key words: Missed nursing care, nursing sensitive outcome, mixed method protocol study, focus group, good practice

Parole chiave: Missed Nursing Care, esiti sensibili all'assistenza, protocollo di studio con metodo misto, focus group, buone pratiche

Abstract

Background. *The Veneto region has recently defined a set of policies on nursing care by determining the needed amount of daily care in minutes and by initiating a systematic measurement of nursing outcomes; also, with a more recent policy, missed nursing care (MNC) has been established as a process measure of interest. To measure the effect of these policies, a research protocol - aimed at evaluating several end points - has been designed, involving a large target population and hospital units. The aim of this manuscript is to briefly present the research protocol and to discuss the public health implications of its expected end-points.*

Study design. *Multi-centre mixed-method study design organised into several phases.*

Methods. *The endpoints of the protocol are: (a) to describe the frequency of MNC as perceived by nurses; (b) to identify contributing factors; (c) to identify practices adopted in low-occurrence MNC units and to assess the effectiveness of implementing them in units with higher levels of MNC; (d) to explore the relationship between the amount of nursing care provided, MNC, and patient outcomes; and (e) to validate a tool that measures MNC as perceived by patients/caregivers. A total of 3,460 nurses, 5,000 patient/day and 160 nursing coordinators of the medical and surgical units of public hospitals in the Veneto Region will be included.*

Conclusions. *Measuring the association between the amount of nursing care and patient outcomes, as well as evaluating the role of MNC as perceived by nurses and patients in hindering or increasing the risk of some patient outcomes can provide a body of evidence capable of further informing policies in the field, both at the national and at the international level. Moreover, emerging good practices capable of preventing or minimising MNC, sharing and implementing them in other units where high levels of missed care are reported and evaluating their effectiveness, can also inform public health policies.*

[1] *Education and Development of Health Care Professions, Azienda Zero, Veneto Region, Padova, Italy*
[2] *Health and Social Area, Veneto Region, Venezia, Italy*
[3] *Department of Biomedicine and Prevention University of Rome "Tor Vergata", Roma, Italy*
[4] *Direction of the Health Care Professions, AULSS 4 Vento Orientale, San Donà di Piave, Venezia, Italy*
[5] *Direction of the Health Care Professions, AOUI Verona, Verona, Italy*
[6] *Direction of the Health Care Professions, AOU Padova, Padova, Italy*
[7] *Direction of the Health Care Professions, AULSS 8 Berica, Vicenza, Italy*
[8] *Department of Medical Science, University of Udine, Udine, Italy*
[9] *Department of Public Health and Diagnostic, University of Verona, Verona, Italy*

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Introduction

The Veneto Region has recently designed and implemented a set of strongly interconnected policies regarding the nursing care. Firstly, a mandatory amount of nursing care at hospital level has been established (1); secondly, with the purpose of assessing the impact of the established mandatory minimum care, a second regional policy aimed at measuring *Nursing Sensitive Outcomes* (NSOs) through specific indicators has been approved (2). Specifically, through a consensus process and on the basis of data already routinely collected and stored in available databases, the following NSOs have been identified as indicators of quality of nursing care in hospitals: in-hospital acquired functional dependence, falls, pressure injuries, in-hospital acquired urinary tract infections, and aspiration pneumonia (2).

More recently, given that the mandatory amount of nursing care and NSOs reflect structural and outcome elements respectively (3), a new policy aimed at measuring the process of nursing care delivery (2) has been established. With the purpose of measuring the effects of the above-mentioned regional policies, a research protocol has been designed. The aim of this manuscript is to present briefly the study protocol and to discuss the public health implications of its end points. Specifically, the primary end points of the study will be: (a) to describe the frequency of *Missed Nursing Care* (hereinafter, MNC) and; (b) to identify the contributory factors to MNC as perceived by nurses; (c) to merge good practices adopted in contexts with a low occurrence of MNC; (d) to evaluate the effects of good practices while sharing and implementing them in contexts where higher degrees of MNC occur; (e) to explore the association, if any, between MNC occurrence as perceived by nurses and some NSOs, and (f) to explore the association(s), if any, between the amount of care delivered on a daily basis, the MNC, and the NSOs.

Secondary end points of the study will be: (a) to validate an instrument measuring MNC as perceived by patients or their caregivers; (b) to explore perceptions of MNC among patients or their caregivers; and (c) to explore the relationship between the amount of care delivered per person per day (in minutes) and the occurrence of NSOs, taking into account the mediating effects of the MNC.

Background

As the amount of nursing care provided has been documented to affect patient's outcomes (4-6), several countries have defined a mandatory minimum nurse-to-patient ratio, or a mandatory level of minutes of nursing care per day (1). However, NSOs have been recognised to be influenced also by some elements relying on the processes of care (7-9). In this context, in the last ten years, the concept of MNC has been studied worldwide (10). Missed nursing care refers to all aspects of clinical, relational and emotional care required by patients that are missed, postponed, or left unfinished by nurses (7). A similar concept, the *Implicit Rationing of Care* (11), has also been established as the process that nurses face daily when they are asked to decide which interventions to omit or delay due to understaffing, lack of time, and skill-mix imbalances (e.g., more nurses' aides than nurses) (8). A third, similar concept, *Care Left Undone*, or *Unmet Patient Needs* (12, 13), has been documented when care procedures are not completed, due to different factors mainly at the organisational and/or managerial levels (10). Alongside these different conceptualisations, MNC has been recognised as the most widespread (11) and it has been introduced into the Italian context in the last five years along with the term *Compromised Nursing Care* (in Italian: ***Cu****re* ***I****nfermieristiche* ***C****ompromesse* or *CuIC*) (9).

According to the available literature, basic care (e.g., hygiene, care assistance during eating), patient's education and

emotional support have been documented as being mostly missed (14-16) with some variations across countries and units. A lack of resources and the unbalanced skill-mix of nursing staff have been established as factors contributing to MNC (7); as a consequence, in clinical settings where the required amount of nursing care is ensured, MNC is expected to be minimal. However, alongside the importance of human resources and the implicit and explicit habits of the team, the priorities given to specific aspects of care by nurses and the degree of collaboration within the team (10) have been documented as affecting MNC. The values and beliefs of each nurse with regard to priorities as well as routines and quality of the working environment (17) have also been recognised as affecting MNC.

Despite its relevance with regards to patients and organization, to the best of our knowledge, no studies to date have attempted to discover practices implemented in contexts where low levels of MNC have been reported, as compared with similar settings where the same amount of human resources are involved in the care processes. In this context, studies based on positive deviant cases (18) can be useful: presenting emerging good practices capable of preventing and/or minimising MNC and sharing and implementing them in other contexts where high levels of MNC are reported, could (a) improve the care offered to patients; (b) increase the capacity of the nursing system to offer the best quality of care; and (c) contribute to the discovery of interventions capable of minimising/preventing MNC, given the lack of evidence in the field.

In addition, the single approach used in investigating the reasons for MNC and its occurrence has to date been based solely upon the perception of nurses using self-report questionnaires (10). Studies have recommended the involvement of patients and their caregivers (9), because their perceptions would inform providers of the care expected and that actually delivered. Furthermore, despite the conceptual clarity available to date (4-6), no large studies have been performed that investigate the consequences of MNC for patients. According to the available evidence, the nurse-patient ratio and the occurrence of MNC have been associated with some NSOs as falls, nosocomial infections, pressure injuries, intra-hospital mortality, adverse events, early readmission, and increased lengths of stay. However, researchers have recommended that further evidence should be gathered in the field (19-21) involving large samples and more mixed-method studies given the complexity of the phenomenon under study (22).

Methods

Study design

A multi-centre mixed-method study design (23, 24) organised in different phases will be performed (see Figure 1**).** Specifically, the main phases and subphases will be organised in the following chronological order to achieve the specific primary and secondary aims:

a) Phase A: in the first Phase, two parallel cross-sectional study designs will be conducted, aimed at measuring the occurrence of MNC by using a validated tool (10, 25) (Phase A1) and at validating the MNC tool among patients or caregivers (Phase A2), respectively;

b) Phase B: in the second Phase, a nested qualitative study design will be performed to merge the practices enacted to minimize and/or prevent MNC in units with low occurrence of MNC as reported in Phase A;

c) Phase C: in the third Phase, three nested parallel study designs based on a pre/post and a cross-sectional study, intended at evaluating the effectiveness of the practices emerged in Phase B as implemented in units with high levels of MNC occurrence (C1), and at exploring associations, if any

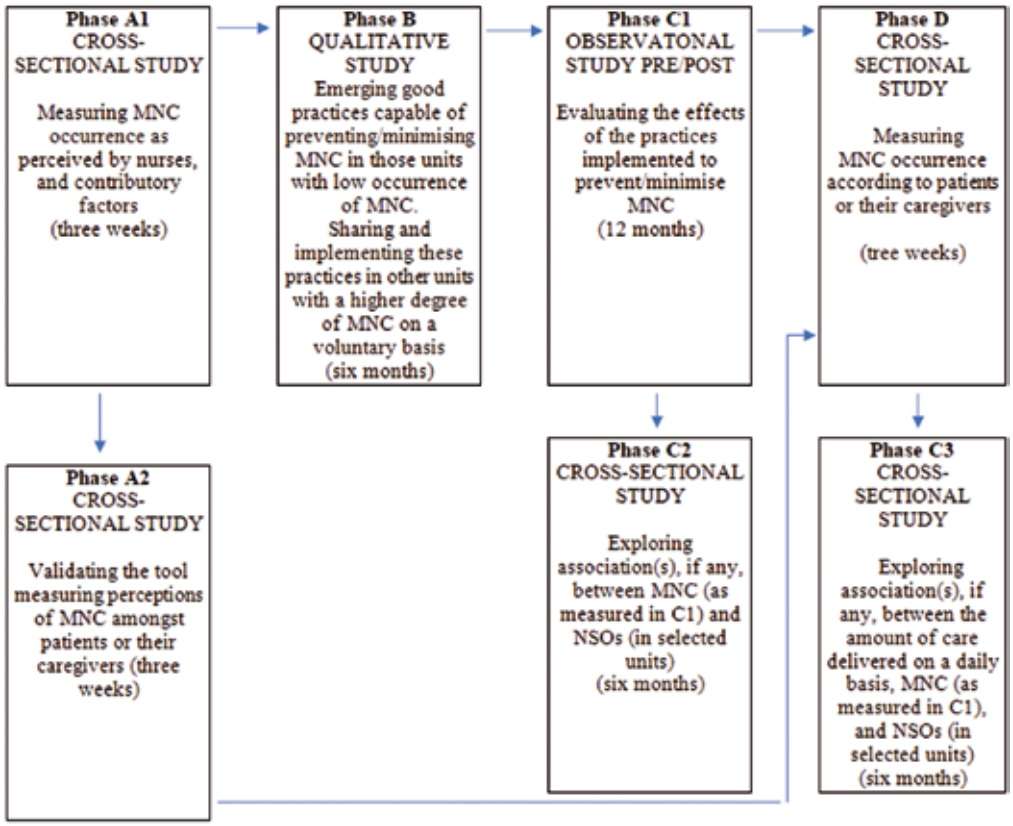

Fig. 1 - **Note.** Phase A1 reflects the name of each phase; MNC: Missed Nursing Care; NSOs: nursing sensitive outcomes. **Legend.** In the vertical session are reported the parallel studies (or subphases), thus performed in the same period of time; horizontally, are reported the studies performed consequentially.

between the MNC occurrence measured and the NSOs by considering also the amount of nursing care (C2 and C3), respectively, will be performed;

d) Phase D: in the fourth Phase, a cross-sectional study will be performed aimed at measuring the MNC as reported by patients with the validated tool (Phase B).

Therefore, the project will involve different phases, and different sub-groups or units in sequential nested studies. However, while the different phases will be conducted consequently, the subphases or nested studies will be performed in the same period of time. The study will be completed in around two years.

In accordance with the consensus conference performed in the field (9), where among others – the aim was to assess the cultural and linguistic validation of the term 'Missed Nursing Care' in order to use an acceptable word also for the public speaking in Italy, the MNC will hereafter be called CuIC (see the explanation above, at the end of the Section "Background").

Setting and sample

The general medicine, geriatrics, general surgery, orthopaedics, and urology units of the following hospitals will be involved: Padua Hospital; Verona Hospital; Veneto Oncological Institute; ULSS 1- Dolomiti; ULSS 2 - Marca Trevigiana; ULSS 3 - Serenissima; ULSS 4 - Eastern Veneto; ULSS 5 - Polesana; ULSS 6- Euganea; ULSS 7 - Pedemontana; ULSS 8 - Berica;

ULSS 9 - Scaligera. In nested studies, the decision regarding units and/or sub-group of nurses to involve will be defined according to the findings of Phase A1; in the case of patients or relatives (Phase A2 and D), units will be involved based on a convenience sample. Moreover, in the last nested study (C2 and C3) database records of patients admitted in a convenience sample of units will be involved.

The following inclusion criteria will be applied:

(a) Level 1: all clinical nurses working in the units who have at least one working shift in Phase A1 and C1, and who participate in the study, will be included; then, a purposeful sample (26) of these will be included in Phase B;

(b) Level 2: in Phase A2, all patients ≥ 18 years, admitted directly to one or some of the units involved (i.e., not transferred or accepted by other hospital units); hospitalised for at least 48 hours; and willing to participate in the study, will be included to validate the tool. Relatives will be involved in the case of patients not able to participate in the data collection process aimed at estimating the CuiC occurrence from their side. At least 10 patients or their caregivers will be expected for each item included (27) in the instrument under validation. Moreover, in the validation study (A2), a sub-group of relatives will be involved with their beloved aimed at estimating the inter-rater agreement and at establishing the ability of relatives to report missed care. In Phase D, patients admitted to a subgroup of units who have been specifically identified and who satisfy the same criteria, will be included.

(c) Level 3: all chief nurses of the units involved (Phase A1) who are working during the study period and who are willing to participate in the study will be included; a purposeful sample of these will be included in Phase B.

(d) Level 4: data stored on the Veneto region health database regarding the NSOs of patients cared for during the study period, and a database populate with the nursing care delivered on a daily basis (in minutes) will be approached for the Phase C2 and C3.

It is expected that an estimated population of 3,460 nurses, 5,000 patients/day and 160 chief nurses leading the units included in the study will be involved.

Variables of interest, data collection tools, and procedures

As reported in Table 1, CuIC occurrence will be measured at the nurses' level, using the Italian Validated Tool measuring the CuIC (10, 25) through the LimeSurvey system over a period of three weeks. After the information about the study aims and procedures has been summarised and reported, the link with the tool will be sent to all eligible nurses through their hospital email addresses.

At the patients or their caregivers' level, the validated tool measuring CuIC among patients or caregivers will be used. This tool will composed by the same items of the Italian Validated Tool measuring the CuIC (10, 25) by adapting them to the patients' perspective (for example: from '*Providing patient hygiene*', to '*Nurses have provided my hygiene*').

At the structural level, data will be collected by interviewing the chief nurses of the unit through the LimeSurvey system in the first week of the study.

At the database level, the NSOs data will be extracted from the Veneto Region's health database. Specifically, data will be collected from the hospital discharge system (in Italian: **S**chede di **D**imissione **O**spedaliera or SDOs) and the clinical risk management databases on the following NSOs: prevalence and incidence of pressure ulcers > 2° level according to the European Pressure Ulcer Advisory Panel Scale (28); fall incidence; hospital-acquired functional dependence measured with the Barthel Index at hospital admission and at discharge; hospital-acquired urinary

Table 1

Study design (Phase)	Population and setting	Variables	Data collection instrument and data collection method
Validation study design: regarding the Tool measuring CuIC among patients or their caregivers (A2)	**Level 2** Patients (or their caregivers) cared for in general medicine, geriatrics, general surgery, orthopaedics and urology units, Veneto region hospitals	- Perceived Compromised Nursing Care and reasons - Sociodemographic data: unit of admission; gender; age; education; marital status; where admitted from (e.g., home, residential structure); previous in-hospital admission(s); type of admission (urgent, scheduled); length of hospital stay; direct care received from family members; overall perception of health (from 0 – *poor* to 10 – *excellent*)	Tool measuring the CuIC among patients or their caregivers Individual interview
Qualitative study design (B)	**Level 1** Nurses working in units with low levels of perceived CuIC	Care practices enacted to minimise/prevent Compromised Nursing Care	Focus groups
Pre/post study design (C1)	**Level 1** Nurses working in units with high levels of CuIC and where good practices have been implemented	The same data collected in A1	Italian Validated Tool measuring the CuIC (10, 27) Socio-demographic section LimeSurvey
Cross-sectional study design (C2)	**Level 4** Data regarding patients cared for during the study period	Prevalence and incidence of pressure ulcers > 2° level (28); fall incidence; in-hospital acquired functional dependence; in-hospital acquired urinary tract infections; aspiration pneumonia incidence; length of hospital stay, destination after discharge (e.g., home, nursing home)	Hospital discharge cards Claims and clinical risk management records
Cross-sectional study design (C3)		No other data collection will be performed: data collected in the different phases and times (A1, C2) will be analysed at the unit level, by taking into account the actual amount of nursing care (in minutes/day) delivered according to the regional law (1, 2), as recorded in the available database	Databases (human resource sigma) recording minutes/day of nursing care CuICs as measured in previous phases Hospital discharge cards and clinical risk management data
Cross-sectional design (D)	**Level 2** Patients (or their caregivers) cared for in general medicine, geriatrics, general surgery, orthopaedics and urology units, Veneto region hospitals	As per step A2, the validated tool will be used	Tool measuring the CuIC among patients or their caregivers Individual interview

Note. Phase A1, reflects the name of each phase; CuIC: Compromised Nursing Care (in Italian); NSOs: nursing sensitive outcomes

tract infections; and aspiration pneumonia incidence (2, 14, 15). The length of in-hospital stays, as well as the destination after discharge (e.g., home, or nursing home) will also be collected. In addition, data for the minutes of nursing care offered on a daily basis will be extracted from the regional database. Table 1 presents a summary of the study design, variables, instruments, and data collection procedures.

Good practice and interventions

According to the findings, good practice capable of preventing/minimising the occurrence of CuIC will be identified in Phase B. Specifically, units with a lower occurrence of CuIC and the practices enacted on a daily basis that emerge through the focus groups will be identified; then, these practices will be benchmarked and shared with other units with a high level of CuIC. In units with a higher occurrence of CuIC and where good practice learnt from other units has been implemented (Phase C1), a new evaluation of the occurrence of CuIC will be performed with the aim of detecting differences, if any, from baseline (A1).

Data analysis

Descriptive analysis will be performed after the quality of the data has been checked. Variables will be described in the form of central trend values (mean, median) and dispersion values (standard deviation [SD], interquartile range [IQR]) according to their distribution, and qualitative ones with absolute and relative frequencies. Then, the association between variables, if any, will be explored with inferential tests (e.g., Wilcoxon–Mann–Whitney; Pearson's chi square) according to the nature of the variables. Generalised linear models for multivariate analyses will be used (29). Internal consistency analysis (Cronbach's alpha) and exploratory and confirmatory factorial analysis (27) will be performed to validate the tool measuring the CuIC according to patients or their caregivers' perceptions. All statistical analyses will be performed using R (Version 3.5.0). The significance of the tests is set for probability values below 5%. A content analysis of good practice enacted to minimise CuIC will be performed on data from the focus groups (30).

Ethics

This research protocol has been approved by the Ethical Committee of the Verona and Rovigo Provinces (protocol 2443/CESC) and will be conducted in agreement with good clinical practice and the Helsinki Declaration (31). Nurses and chief nurses will be free to participate, and no incentives will be offered to encourage them to do so; they will all be informed of the study aims and the data collection procedures. Consent to participate will be requested in the first section of the online questionnaire. Information about the study aims and procedures will be provided in the unit and in the hospitals as a strategic action in the research protocol's implementation. Patients (or their caregivers) will be interviewed after the aims of the study and data collection procedures have been explained to them. The data will be anonymized beyond unit level and will be gathered by researchers who are not involved in patients' care, thus leaving patients (or their caregivers) free to express their views. Units will be informed about the findings through *ad hoc* meetings. The study has no potential risks, given that it will not directly alter clinical practice; specifically, only improvement in the quality of care is expected.

Study potential limitations

Despite its novelty, the study will have some limitations. First, it involves a large sample of units, nurses and patients: therefore, the quality of the data collected might be affected by local variations. Due to this, educational strategies aimed at providing a homogenous data collection (regarding for example the patient's interviews, the

registered NSOs in the records stored in the database) will be provided. Second, the project will be performed in different steps and will have > 2 years in duration. Therefore, different endogenous and exogenous factors (e.g., nurses turn over, changes in the models of care, health care reforms, COVID19 pandemic) will influence both the methods and the findings. Researchers will record all appreciable changes that might affect the research process as confounders in order to discuss their implications on the findings; moreover, robust data analysis will be performed to discover and take into account, if any, confounders at the individual, unit and hospital levels. However, it is clear that the complexity and the risk of confounders is embodied and non-avoidable in health service research processes (32). Third, according to the nature of the study, the sample size has not been established *a priori*; however, in order to prevent low response rates that have been documented in similar studies regarding errors of omissions (e.g., 33-35), an ample process of engagement of potential participants will be performed.

Public health implications

Developing policies to improve the quality and quantity of nursing care has become a priority in recent years, because they have the potential to influence significantly citizens' well-being and quality of life. Excessive dependence on others in daily living activities due to the functional impairments acquired during hospitalisation, short- and long-term effects of hospital-acquired urinary infections, pressure ulcers, and falls that can lead to increased mortality, are just a few examples of the consequences of poor care at the individual and public health level (1, 2, 7-9). Evidence-based policies on safe staffing in acute adult inpatient wards are therefore dramatically needed. However, the evidence is still limited, due to the lack of research in the field. The studies that exist have involved small samples, and mainly evaluate the amount of care and not its processes.

In line with the available international experiences (19-21), the Veneto region has developed a set of policies that address firstly the minimum acceptable amount of nursing care and secondly the measurement of NSOs. In addition, the region has also developed the present study protocol aimed at detecting shortfalls in the nursing care process and at improving quality of care, by implementing a set of good practices that have already been put in place in some units with the aim of minimising or preventing MNC. Measuring the association between staffing and patient outcomes, as well as evaluating the effects of MNC on NSOs, may provide a body of evidence to further inform policies in the field, both at the national and international level. Moreover, discovering good practices that prevent or minimise MNC, sharing and implementing them in contexts where high levels of MNC are reported, and evaluating their effectiveness will also inform policies regarding the care process.

Riassunto

Valutazione degli effetti di una serie di policies riguardanti le cure infermieristiche nella Regione Veneto: protocollo di ricerca e implicazioni per la salute pubblica

Premessa. La Regione Veneto ha recentemente definito una serie di policies in materia di assistenza infermieristica fissando la quantità di cure giornaliere e avviando una misurazione sistematica degli esiti sensibili alle cure infermieristiche sui pazienti; con una policy più recente, anche le Missed Nursing Care (MNC) sono state considerate. Per misurare l'effetto di queste politiche, è stato progettato un protocollo di ricerca che coinvolge una ampia popolazione di infermieri, pazienti e unità ospedaliere finalizzato a valutare numerosi outcomes. Presentare il protocollo di ricerca e discutere le implicazioni per la salute pubblica è la finalità di questo articolo.

Disegno dello studio. È stato pianificato uno studio mixed-method, organizzato in più fasi.

Metodi. Lo scopo del protocollo è (a) descrivere la frequenza delle MNC percepite dagli infermieri; (b) identificare i fattori contribuenti valutandone anche l'evitabilità; (c) identificare le pratiche adottate nei contesti a bassa occorrenza di MNC e valutare l'efficacia di implementazione delle stesse in unità con più elevati livelli di MNC; (d) esplorare la relazione tra la quantità di cure erogate, le MNC e gli esiti sui pazienti; nonché (e) validare uno strumento che misura le MNC percepite da pazienti. Saranno inclusi 3.460 infermieri, 5.000 pazienti / giorno e 160 coordinatori infermieristici delle unità di medicina e chirurgia degli ospedali pubblici della Regione Veneto.

Conclusioni. Misurare l'associazione tra la quantità di cure infermieristiche e gli esiti dei pazienti, nonché valutare il ruolo delle Missed Care sugli esiti clinici può fornire un insieme di prove in grado di informare future policies sia a livello nazionale che internazionale. Inoltre, le pratiche capaci di prevenire o ridurre al minimo le MNC, la loro condivisione e implementazione nelle unità in cui sono segnalati elevati livelli di MNC per valutarne l'efficacia, può informare le politiche di salute pubblica.

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Corresponding author: Alvisa Palese, PhD, Department of Medical Sciences, University of Udine, Viale Ungheria 20, 33010 Udine, Italy e-mail: alvisa.palese@uniud.it