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Info Authors :

¹ Nurse in Asl4² Nurse responsible of primary care department at Asl5³ Nurse and clinical tutor in Asl5⁴ Responsible in charge for pole of La SpeziaFederici L.¹ Nardini M.² Nativi O.³ Cantinotti E.⁴

ICU PATIENT COMFORT AND CARE IN THE ABSENCE OF DEEP SEDATION: A CROSS SECTIONAL OBSERVATIONAL STUDY

INTRODUCTION

Humanization of care is understood as “attention to the person in his or her totality, composed of organic, psychological and relational needs” (1).

Article 4 of the Code of Ethics of Nursing, Caring Relationship, specifies the correct nursing approach towards the patient: “In professional action, the nurse establishes a caring relationship, including listening and dialogue.

He/she ensures that the person being cared for is never neglected by involving, with the consent of the person concerned, his/her relatives and other professional and institutional figures. Relationship time is care time”. Hospitalization is almost always a dramatic experience, even more so in intensive care, both for the person concerned and for his or her family. In the ICU, the patient is often deeply sedated, mechanically ventilated, fed by enteral or parenteral nutrition, and then entrusted to mechanical management to meet his or her physiological needs, since he or she is not self-sufficient.

This modern, or rather “hyper-technological” approach to care succeeds in replacing many of the human faculties by meeting the patient’s basic needs, while at the same time depriving them of others, making care necessarily dehumanizing.

Ninety-eight per cent of intensive care units in Italy have restrictive policies on patient visits by relatives and carers, adopting the ‘closed intensive care unit’ model, which in turn creates barriers at the level of the relationship between family and patient (2).

In the past, the ‘closed ICU’ model has always been favored because it was thought to have an impact on patient mortality and the increase in nosocomial infections (NIH).

At present, however, there is no scientific basis for restricting family access to the ICU; on the contrary, an open ICU model would meet the needs of family members and patients (3).

Systematic reviews have shown that family support in the ICU reduces length of stay without affecting mortality (4), and that flexible visiting hours in the ICU have the potential to reduce delirium and anxiety (5).

The eCASH protocol (6) represents a new paradigm of care for ICU patients who do not require deep sedation, the acronym stands for: early, comfort, analgesia, minimal sedation and maximum humane care, this to promote sleep development, early mobilization and better communication of patients with staff and relatives; avoid long-term complications caused by ICU stay (e.g. isolation, confusion), contribute to patient rehabilitation and improve the clinical well-being of patients both during and after ICU admission.

MATERIALS AND METHODS

This is a multicenter, cross-sectional, descriptive, observational study conducted between March and May 2021.

A careful literature review and search was conducted for existing and previously validated instruments that would investigate nurses' knowledge of the eCASH protocol ⁽⁶⁾ ⁽¹⁾ and its three core elements (pain, sedation, and humanization of care).

As no instruments were found in the literature to assess nurses' knowledge of the three elements of the protocol, a questionnaire was independently developed. The questionnaire was reviewed and approved for data collection for study, publication/research purposes, in compliance with privacy regulations, by the Director of the S.C. Planning and Quality, Accreditation and Training and the Director of the S.C. Direzione Medica di Presidio Ospedaliero DMPO Asl 5.

In order to make the study more rigorous, test questionnaires were printed in paper format and left at the disposal of the S.C. Resuscitation COVID San Bartolomeo di Sarzana Establishment of Asl 5 for a period of two weeks, in order to process the face validity. In the introduction to the questionnaire, they were asked to answer the questions with the final aim of making suggestions and/or general corrections through face validity.

Specifically, in face validity, the questionnaire recipients are asked to evaluate the form and terms used to construct the questions, i.e., whether the questions are clear, whether the questions contain difficult or offensive terms, or whether the questions should be rephrased.

With face validity, several changes to the questions and answers were suggested by the nurses.

The changes made within the questionnaire, thanks to the professionals' opinion on face validity, resulted in a validated instrument.

The total number of questions in the validation questionnaire was 31 and all 31 were confirmed by the professionals. As this is a national study, the study group added a question to the questionnaire

asking about the professional's place of work, whether northern, central or southern Italy.

In total, therefore, there are 32 questions in the new questionnaire. The validated questionnaire was created using the Google Forms platform. Participation in the study was voluntary.

In the introduction of the questionnaire, the project and the study were specified, as well as the processing of their data, with reference to Legislative Decree No. 196/2003 on the protection of personal data. A sample of 130 nurses completed an online questionnaire distributed via the Internet on a voluntary and anonymous basis.

The inclusion criteria for completing the questionnaire were nurses currently working in the ICU, regardless of months or years, without distinction of contract type (fixed/indefinite), working hours (full-time or part-time), gender and age. ICU nurse coordinators were also included in the study.

The questionnaire consisted of a first section with socio-demographic questions (age, gender, education, work experience, work position, work location) and three further sections with questions to assess the nurses' knowledge regarding:

- Humanisation of care, 7 items
- Pain, 6 items
- Sedation, 3 items
- The eCASH protocol, 10 items

RESULTS

SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE

The validated questionnaire was completed by 130 ICU nurses. 78.5% of nurses completed the questionnaire completely while 21.5% completed it partially.

The socio-demographic characteristics of the sample are shown in **TABLE I**.

TABLE I

SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE

	N:	130
Gender	Gender:	
	-Male	27,9%
	-Female	72,1%
Age Range	-21-30	55,4%
	-31-40	22,3%
	-41-50	13,1%
	-51-60	8,2%
	-Over 60	1%
Work-experience	0-10 years	65,4%
	11-20 years	18,5%
	21-30 years	10%
	Over 30 years	6,1%
Degrees	Bachelor's degree or equivalent	63,6%
	Master's degree or specialisation	29,4%
	Master's degree	6,2%
	Master's degree (2nd level)	0,8%
Job position	ICU nurse	99,2%
	ICU head nurse	0,8%
Work location	North Italy	69,8%
	Central Italy	23,2%
	South Italy	7%

HUMANIZATION OF CARE

The responses to the humanization of care section show that 82% of respondents agree that the presence of a family member who has been properly trained in the use of PPE and how to approach/contact the patient in the ICU does not increase the risk of infection for the patient (FIGURE I).

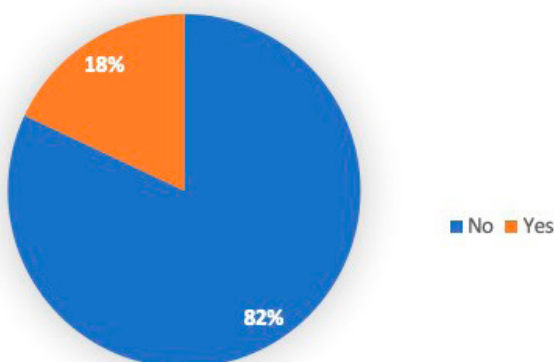


Figure I

96.9% of nurses who participated in the study believe that humanizing care is important or very important (FIGURE II).

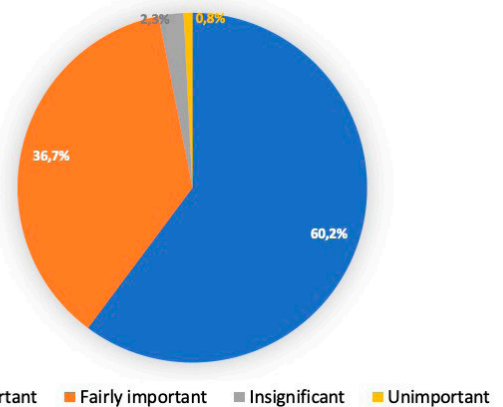


Figure II
Importance of humanizing care, according to nurses.

From the data, we find that less than half of the nurses who participated in the study, know the actual average opening time for visits to ICUs in Italy “two hours” (1) (FIGURE III), and that less than half of the nurses report working in an open model ICU (FIGURE IV).

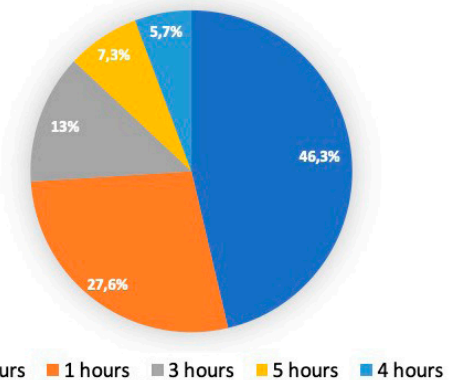


Figure III
Nurses' knowledge of the average openness of Italian ICUs to visitors.

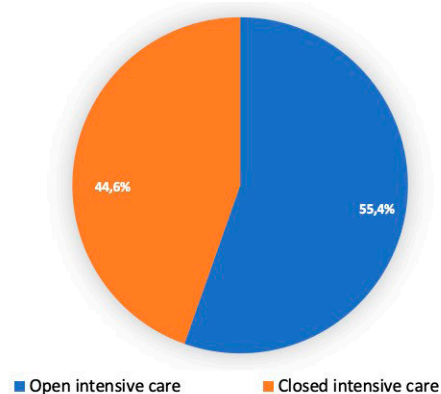


Figure VI
ICU model in place where nurses work.

PAIN

With regard to the answers related to the section on analgesia, it is important to mention first that in 1996 the Citizen Nurse Pact emphasized the importance of attention to the person, to his or her autonomy, to his or her dignity, and to his or her closeness in times of pain.

Through a long regulatory process, this led to the enactment of Law 38/2010, Article 7.

Despite the fact that eleven years have passed since this law was enacted, 46.5% of respondents say they are not familiar with it (**FIGURE V**).

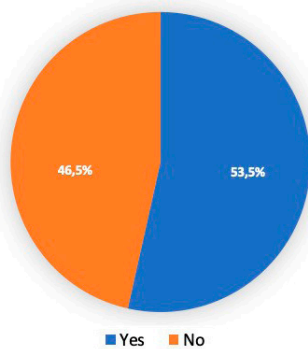


Figure V
Nurses' knowledge of Law 38/2010 on Pain.

Analyzing the use or misuse of pain rating scales on the basis of the patient's state of consciousness, it was found that: in the conscious patient, the scales most used by the participants (being able to choose more alternatives) are: for 82.3% the Numeric Pain Rating Scale "NRS", for 62.3% the Visual Analogue Scale "VAS". While in the unconscious patient, the most used are Behavioral Pain Scale "BPS" for 66.1%, Critical-Care Pain Observation Tool "CPOT" scale for 48.8%. The data show that 12.6% of the respondents indicated the VAS and 6.3% the NRS as scales suitable for assessing the pain of the unconscious patient.

SEDATION

Questions in the sedation section revealed a near-optimal level of knowledge about sedation modalities and medications used for sedation.

ECASH PROTOCOL

Finally, it is important to note that 9.4% of respondents indicated that they were aware of the eCASH protocol ^{(6) (2)}, even though this protocol is innovative and little known, with very few publications on it.

CONCLUSIONS

The results of the study provide a relative overview of nurses knowledge regarding the three elements of the eCASH protocol (pain, sedation, and humanization of care) ^{(6) (3)} and identify some gaps. Daily assessment of pain intensity leads to better quality of life for patients after discharge.

Pain measurement is crucial for the assessment and therapeutic strategy to control it.

In order to choose the most appropriate drug treatment, the primum movens lies in the correct assessment of pain intensity, severity, and duration. In general, there are several pain assessment scales: one-dimensional scales (indicated for acute and chronic pain) and also multidimensional scales (indicated for chronic pain).

The "gold standard" in pain assessment is patient self-report, which can be performed in conscious patients. However, patient self-report is not always possible due to clinical conditions (deep sedation, mechanical ventilation).

Literature and studies show that the two most appropriate tools for patients who are unable to communicate their pain level because they are unconscious or deeply sedated (usually patients admitted to the ICU) are the "Behavioral Pain Scale (BPS)" and the "Critical Care Pain Observation Tool (CPOT)"⁽⁷⁾.

After analyzing the use or misuse of pain rating scales based on the patient's level of consciousness, it is found that in the unconscious patient, three of the most commonly used scales by the participants are: for 66.1% the Behavioral Pain Scale "BPS", for 48.8% the Critical-Care Pain Observation Tool "CPOT" scale. The data show that 12.6% of respondents indicated the VAS and 6.3% the NRS as scales suitable for assessing pain in the unconscious patient, both scales being suitable for the alert and oriented patient.

These latter data reveal a training gap that needs to be addressed. Before disseminating the eCASH protocol for its eventual implementation, it would be appropriate to fill the knowledge gaps related to analgesia (its management and treatment) and to implement specific training to ensure greater humanization of care. Law 38/2010 art.7 pivotal

point of pain management and treatment obliges companies to train staff on the detection and management of pain itself, in particular: there is an obligation to report the detection of pain within the medical record; "in the medical and nursing section, used in all health facilities, the characteristics of the detected pain and its evolution during the hospitalization as well as the analgesic technique and drugs used, dosages and the results obtained must be reported.

In relation to the above, although thirteen years have passed since the enactment of this law, 46.5% of respondents said they were not familiar with it. 96.9% of the nurses who participated in the study believe that humanizing care is important or very important. Thus, 46.3%, less than half of the nurses who participated in the study, know the actual average of opening to visits of intensive care units in Italy "two hours"^{(2) (3)} and 44.6%, again less than half of the nurses say they work in an open model ICU.

The data show a discrepancy between the importance that nurses attach to openness to visits, which promotes greater humanization of care, and the reality of the facts.

As highlighted in our study, in order to improve the knowledge and individual compliance of ICU nurses with the three elements characterizing the *eCASH* protocol, and to give consistency to the work done, it would be useful for our patients in the future to develop a pilot project, limited to the areas best studied (Northern Italy), aimed at training nurses on the new *eCASH* protocol.

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